A COMPARATIVE STUDY OF 3 D CURVED STRUT MINIPLATE VERSUS FOUR HOLE MINIPLATE IN OPEN REDUCTION AND INTERNAL FIXATION OF ISOLATED UNILATERAL ANGLE FRACTURES OF MANDIBLE

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY
CHENNAI – 600 032

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This is to certify that the Dissertation entitled **"A COMPARATIVE STUDY OF 3 D CURVED STRUT MINIPLATE VERSUS FOUR HOLE MINIPLATE IN OPEN REDUCTION AND INTERNAL FIXATION OF ISOLATED UNILATERAL ANGLE FRACTURES OF MANDIBLE"** is a bonafide work done by **Dr.B.MANONMANI.**, Post Graduate student (2014-2017) in the Department of Oral and Maxillofacial Surgery, under the guidance of **Dr. D. DURAIRAJ, M.D.S.,** Professor, Department of Oral and Maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003.

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled **"A COMPARATIVE STUDY OF 3 D CURVED STRUT MINIPLATE VERSUS FOUR HOLE MINIPLATE IN OPEN REDUCTION AND INTERNAL FIXATION OF ISOLATED UNILATERAL ANGLE FRACTURES OF MANDIBLE"** is a bonafide and genuine research work carried out by me under the guidance of **Dr.D.DURAIRAJ, M.D.S., Professor,** Department of Oral and Maxillofacial Surgery, Tamilnadu Government Dental College and Hospital, Chennai - 600003**.**

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Last but not least I would like to seek the blessings of the almighty without whose grace this endeavor wouldn’t be possible.

TRIPARTITE AGREEMENT

This agreement herein after the "Agreement" is entered into on this day _____ between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai - 600 003, (Herein after referred to as, the college")

And

Dr. D. DURAIRAJ, 56 years working as P**rofessor** in the Department of Oral & Maxillofacial surgery, at the college, having residence address at No- 3/19,1st street, Raghava nagar, Moovarasampet, Chennai - 91. (Herein after referred to as the "Principal investigator")

And

Dr. B. MANONMANI, aged 39 years currently studying as **Post Graduate Student** in the Department of Oral & Maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, Chennai-03 (Herein after referred to as the "PG Student and co-investigator").

Whereas the PG student as part of her curriculum undertakes to research on "**A COMPARATIVE STUDY OF 3 D CURVED STRUT MINIPLATE VERSUS FOUR HOLE MINIPLATE IN OPEN REDUCTION AND INTERNAL FIXATION OF ISOLATED UNILATERAL ANGLE FRACTURES OF MANDIBLE"** for which purpose the Principal Investigator shall act as principal investigator and the college shall provide the requisite infrastructure based on availability and also provide facility to the PG student to the extent possible as a Co-investigator.

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1.

2.

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20-02-2016

Ref: R.C No.0430/DE/2015 dated 03-10-2015 o/o Principal, TNGDC
Sub: IEC review of the research proposals,

Title of the work: A Comparative study of 3D curved strut Miniplate versus 4 hole Miniplate for open reduction and internal fixation of isolated unilateral angle fractures of mandible

Principal Investigator: Dr. B. MANONMANI
II yrMDS.,

Department : Department of Oral and maxillofacial surgery
Tamil Nadu Government Dental College & Hospital, Chennai-3

Thank you for submitting your research proposal , which was considered at the Institutional Ethics Committee meeting held on 17-10-2015, at TN Govt. Dental College and the documents related to the study referred above were discussed and the modifications done as suggested and reported to us through your letter dated 19-02-2016 have been reviewed.

The decision of the members of the committee , the secretary and the Chairperson IEC of TN Govt. Dental College is here under:

Approved	Approved and. advised to proceed with the study
Approved with suggestions	----------
Revision	----------
Rejected	----------

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ABSTRACT

OBJECTIVES: The purpose of this study is to compare the clinical outcomes of patients treated with 3-dimensional curved strut miniplates versus four hole miniplates for open reduction and internal fixation (ORIF) of isolated unilateral angle fractures of mandible.

MATERIALS AND METHODS: In this prospective study 10 patients with isolated, unilateral angle fractures of the mandible were included and divided randomly into 2 groups containing five patients in each group. All patients were treated under local anesthesia. In Group I, patients were treated with a single 2 x 4 hole conventional straight titanium miniplate and four 2 x 8 mm titanium screws. In Group II, patients were treated with single 2x8 hole 3-dimensional curved strut titanium miniplate and four 2 x 8 mm titanium screws using transbuccal trocar and cannula system. The parameters evaluated were intraoperative time, surgical site accessibility, adaptability of plates, stability of facture fragments, occlusal discrepancy, neurosensory deficit, fracture healing , wound infection and dehiscence.

STATISTICAL ANALYSIS: SPSS. Version 16.0

RESULTS: Plate adaptability and fragment stability was superior in patients treated with 8 hole 3- dimensional curved strut miniplate [P value-0.038]. All patients in this study had preoperative occlusal discrepancy. Mild occlusal discrepancy was observed in one patient in group I postoperatively and was successfully managed by guiding elastics for a period of 10 days. At the end of the follow up period of 6 months fracture healing was satisfactory with no evidence of malunion or nonunion in both the groups.

3-Dimensional curved sturt titanium miniplate used in this study provides good plate adaptability and easy accessibility to the surgical site and three dimensional stability in the management of isolated mandibular angle fractures than four hole straight miniplate. There were no incidence of surgically created neurosensory deficit, wound infection and dehiscence in both these plating systems. The small sample size and limited follow-up period could be considered as the limitation of the study.

CONCLUSION: 3-Dimensional curved sturt titanium miniplate offers superior plate adaptability and fracture fragment stability than conventional 4 hole miniplate in the management of mandibular angle fractures without any significantly different overall complication rate. The small sample size and limited follow-up could be considered as the limitations of this study.

KEY WORDS: Mandibular angle fracture, 3-Dimensional curved strut plate, straight miniplate, Transbuccal trocar and cannula.

ABBREVIATIONS

MMF	-	Maxillo Mandibular fixation
OPG	-	Orthopantamogram
ORIF	-	Open reduction and internal fixation
SD	-	Standard deviation
IAN	-	Inferior alveolar nerve
FEA	-	Finite element analysis
LA	-	Local Anaesthesia

INTRODUCTION

Maxillofacial fractures are one of the most common injuries reported in the hospitals worldwide. The prominent position of mandible on the face makes it more vulnerable for trauma. Mandibular fracture causes significant facial deformity and loss of masticatory efficiency and speech. Next to condylar neck fracture, angle fractures are the second commonest fractures of mandibular fractures and the incidence is 23% to 42% of all mandibular fractures[1].

Motor vehicle accidents, interpersonal violence are the most common causes of maxillofacial injuries in last few decades. The other causes are sport related injuries and falls.[2]

Mandibular angle fractures generate more complications than other mandibular fractures and accounts for 0%- 32%[3]. The cross-section of bone in mandibular angle is less when compared with anterior mandibular regions, which provides less surface contact area to allow stabilization between fracture fragments. The surgical access is less in angle region when compared to anterior mandible fractures. As fractures in angle region is posterior to the molar teeth ,optimal stabilization by maxillomandibular fixation alone is not possible.[4] Presence of third molar in angle region may prevent proper fracture reduction , decreases contact area between bony surface , interrupt the vascularity to fracture site and may be source of infection.[5]

Management of angle fracture is further complicated by opposing forces created by elevators (masseter, medial and lateral pterygoid muscles and

temporalis) and depressors (geniohyoid, genioglossus, mylohyoid and digastrics muscles) in angle region.[4]

The treatment objective for mandibular fractures include the achievement of anatomical form and function with priority to achieve proper occlusion. The management of mandibular angle fractures has gone through various stages of evolution ranging from conservative to open treatment. Conservative management is achieved by the reduction of fracture segments with adequate occlusion with the help of direct or indirect interdental wiring to accomplish immobilisation in that position by means of maxillomandibular fixation for 4 to 6 weeks. The demerits in conservative treatment method includes inconvenience to the patient and the possibility of airway obstruction. The prolonged MMF can lead to masticatory muscle atrophy.

Open reduction and internal fixation can eliminate or reduce the period of immobilization and allows for early return to jaw function. Several internal fixation methods including lag screws, reconstruction plates, dynamic compression plates, miniplates were studied with great variation in complication rate, especially infections and both Champy and AO/ASIF philosophy have been applied in varying combinations.

As larger plates were applied in AO/ASIF philosophy by extraoral approach for the treatment of mandibuar angle fractures, which may increase the risk of injury to important anatomic structures in this region, the formation of scars and larger plates are difficult to adapt. Despite miniplates simplifying the surgery and decreasing the morbidity, authors have turned their attention to the

use of a variety of small plates with monocortical screws as many of them failed to overcome the predictability of rigid fixation with a 2.4-mm system and reconstruction plates, especially in fractures that cannot be adequately reduced.[6]

Stability of 3-dimensional plates depends on the format of the plate unlike traditional plates which depends on the thickness of the plate. The 3D plates can be considered a two-plate system, with two miniplates connected by reinforcing vertical struts. The geometrical shape of 3D strut plates allows the usage of more number of screws, three dimensional stability and increased resistance to torsional forces while maintaining low profile and malleability of the miniplates[7.] Simultaneous stabilization achieved in both the tension and compression zone while using 3D plates when compared with conventional miniplates.

The 3-D curved strut plate allows almost no movement at the superior and inferior borders with manual torsional and bending forces, when compared with a single linear plate application at the superior border which allows movement along the long axis of the plate with bucco-lingual splaying and creation of gap along the inferior border. In 3D curved strut plate screws were placed in a box configuration on either side of the fracture line which creates a broad platform which may increase the resistance to torsional forces along the plate axis[7] .

This prospective study was conducted on 10 Patients who reported to the Department of Oral & Maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, with isolated mandibular angle fractures. Out of ten, five patients were treated by four hole conventional straight titanium miniplate with gap and five patients were treated by eight hole 3dimensional titanium curved strut plates using transbuccal trocar and cannula.

Adaptability of plates, accessibility of surgical site and time taken for the procedure were assessed intraoperatively. Preoperative and postoperative occlusal discrepancy, mouth opening and neurosensory deficit were assessed. Stability of fracture fragments, wound infection and dehiscence and bone healing were assessed post operatively and the results were compared between group I and group II.

AIM AND OBJECTIVES

The purpose of this study is to compare the clinical and radiological outcomes of patients treated with 3-dimensional curved strut titanium miniplates versus four hole miniplates for open reduction and internal fixation (ORIF) of isolated unilateral angle fractures of mandible.

OBJECTIVES:

The following parameters were assessed in both the groups and compared for a period of six months postoperatively.

i. Surgical accessibility
ii. Adaptability of plates
iii. Intra operative time
iv. Stability of fracture fragments
v. Occlusal discrepancy
vi. Wound infection and dehiscence
vii. Neurosensory deficit
viii. Fracture healing

REVIEW OF LITERATURE

The mandible is the second most commonly fractured structures in the maxillofacial skeleton[8]. There are many possible causes for mandibular fractures. Assaults (53.7%) and motor vehicle accidents (28.1%) are the most common factors for mandibular fractures Male patients accounts for 84% of all mandibular fractures , with angle of mandible is the most common location[9].

Ellis[10] (1985) in his study has stated that mandibular angle fractures are the second most common fractures caused by assaults and the third most common fractured region in the event of falls.

Alleyson[11] (2008) in his study stated that angle fractures are the most common fracture which accounts for 30% of all mandibular fractures.

Pathologic fractures can result from conditions such as osteo-radionecrosis, bisphosphonates-related osteonecrosis, and benign or malignant tumours or cysts that weaken the structure of angle region to the point where a fracture occurs from minimal or no trauma[12].

CLASSIFICATION AND MANDIBULAR ANGLE FRACTURE PATTERN

The mandibular angle is best described as an anatomic region rather than a precise anatomic location. This area is designated as a triangular area with the superior edge at the junction of the horizontal body and the vertical ramus where the third molar is or was usually located. The anterior border of the masseter muscle forms the anterior border of the triangle and the posterior border of the triangle is formed by an oblique line extending from the third molar region to the posterior superior attachment of the masseter muscle[13].

Fractures through the mandibular angle can be classified in a variety of ways. Angle fractures described as either closed or open. A fracture which does not communicate with the outside environment is classified as closed fracture and the one which is partially or completely exposed to the oral cavity or extra oral surface through overlying tissues is called open fractures. Extra oral open fractures rarely occur except in high-velocity or penetrating injuries. Intraoral open fractures are more common due to gingival laceration at the superior border in angle region. Connection of the fracture to the mouth through the periodontal ligament also creates an open fracture[12].

Angle fractures can also be classified as simple or comminuted. In Simple fractures break in continuity of bone involves a single line whereas in comminuted fractures multiple breaks through the bone is observed. Most common etiologic factor involved in comminuted fractures is often high impact trauma, such as gunshot wounds and high-speed motor vehicles accidents[12] .

According to degree of fracture separation fractures are classified as complete and green stick fractures. In complete fractures the separation occurs in both the medial and lateral cortices. In green stick fractures disturbance in bone continuity observed in only one cortical plate are rare[12] .

Mandibular angle fractures can also be classified as favourable or unfavourable. A favourable fracture occurs when the masseter and medial pterygoid muscle action on the proximal and distal segments of the fracture help to reduce it. The more common unfavourable fracture involves separation of the proximal and distal segments due to muscle pull. An unfavourable fracture is

further classified into horizontally or vertically unfavourable. In horizontally unfavourable fracture, the action of the masseter and medial pterygoid muscles distracts the proximal segment superiorly while the suprahyoid muscles act to distract the distal segment inferiorly. In vertically unfavourable fracture, the fracture pattern allows for the distal segment to be pulled medially by the medial pterygoid muscle[12] .

DIAGNOSIS

Extraoral examination begins with a visual inspection. Swelling, ecchymosis, and step deformity and tenderness on palpation at the inferior border may be a sign of an angle fracture[11].

A thorough cranial nerve examination should be done with special attention to potential changes in the third division of the fifth cranial nerve. The mandibular angle fractures with some degree of displacement are likely to cause hypoesthesia, anesthesia, or dysesthesia of inferior alveolar nerve[12].

Facial nerve (cranial nerve VII) injury angle fractures are rare but this can occur with penetrating trauma. These findings should be documented in the preoperative evaluation as a baseline for postoperative patient monitoring[12] .

Ecchymosis, gingival lacerations, and bleeding in the posterior buccal and lingual vestibules can be observed in intraoral examination. Evaluation of the occlusion may show a malocclusion, with premature tooth contact on the fractured side and an open bite on the contralateral side. In bilateral mandibular angle fracture patients open bite in anterior region and displacement of the tooth-bearing segment observed in posterior region[12] .

In radiographic examination at least two views of the mandible should be obtained when using plain films and should be perpendicular from each other to ensure proper evaluation. The use of plain films has fallen out of favour due to the availability of CT scans. Axial CT scans with sagittal and coronal reconstructions provide excellent visualization of all dimensions of the fracture and are becoming the gold standard in diagnosis[12] .

TREATMENT PROCEDURES

The examination, diagnosis and treatment of mandible fractures began as early as 1650 BC as evidenced by the **Edwin Smith Papyrus[14]**. **Hippocrates[15] ,** the "Father of medicine," was the first to describe the basic principles of modern fracture repair, reduction and stabilisation. He describes the use of circum dental wires and external bandaging for reapproximation and immobilization of fracture fragments.

Salerino in 1180 from Italy in his textbook described the importance of occlusion in the management of mandibular fractures. However, it was **Guglielmo Salicetti[16] in 1492**, in his book Cyrurgia presented concept of maxilla mandibular fixation by stating "tie the teeth of the uninjured jaw to the teeth of the injured jaw". Although a fundamental concept in contemporary facial fracture management, Salicetti's concept of MMF disappeared for centuries until **Gilmer[17] in 1887** applied the technique clinically and described its utility in more detail .

In 19th century, **Buck[18],** used an iron loop and **Kinlock** used silver wire for open reduction of mandibular fracture treatment. **Gilmer[19] in 1881**, described the use of two heavy rods placed on either side of the fracture that were wired together.

Schede is credited with the first use of a true bone plate made of steel and secured with four screws. In the **1960s, Luhr[20]** developed the Vitallium mandibular compression plate through his research on rigid fixation of the facial skeleton.

TYPES OF FIXATION

Since the 1970s, two main schools of thought have been advocated for the open reduction and fixation of fractures. They are Arbeits-gemein-schaft fur Osteosynthesefragen/Association for the Study of Internal Fixation (AO/ASIF) using rigid compression plating and semirigid noncompression miniplates[21] .

AO/ASIF advocated that total rigidity and compression without inter-fragmentary mobility is required to achieve primary bone healing during active use of the mandible[21].**Luhr** also recommended rigid fixation using large bone plates with bicortical screws.

Michelet[21] et al., **1973** reported the mandibular fracture treatment using small, easily bendable non compression bone plates, placed transorally, and attached with monocortical screws[21]. This technique was validated by **Champy et al[22] in 1978**., who performed several investigations with a miniplate system. In their experiments, they determined the "ideal lines of osteosynthesis" for more stable fixation of bone plates. For mandibular angle fracture management "Ideal line of osteosynthesis" is located along the superior border of mandible. In miniplate osteosynthesis absolute immobilization was deemed unnecessary.

Spiessel[23] in 1979 recommended the use of an arch bar when the fracture is within the dental arch. The arch bar acts to prevent fracture displacement at the superior border. Along the alveolar ridge, when the fracture is beyond the dental arch, he recommended the use of a 2-hole tension band plate as found by **Kroon et al[24], in 1991** and **Rudder-man et al[25], in 2008.**

Kroon et al[24] in 1991 used polyurethane mandibles to examine the stability of miniplate fixation of simulated fractures of the mandibular angle. They loaded the mandible in various functional positions and found bending or torsional forces were not sufficiently controlled by single miniplate fixation. These results were quite different from those obtained in Champy et al study using simple models. Furthermore, when the ipsilateral molar was loaded, the zones of tension and compression reversed, causing a gap to form at the inferior border, where no fixation device was placed. Similar results were obtained by **Shetty et al[26] in 1995** in the study conducted to compare the dynamic stability of six internal fixation schemes for angle fractures. They showed that a single miniplate for fractures of the mandibular angle applied according to the principles of Champy" offered the least resistance to displacement of the six methods tested.

Levy et al[27], in 1991compared single versus two miniplates for mandibular angle fracture without post surgical MMF. He concluded that single miniplate may not be efficient and recommends second miniplate fixation at the lower border of mandible. **Choi et al[28] in 1995 and Shetty et al[26] in 1995** have advocated that two plates are more stable than single plate fixation for angle fractures.

Fox and Kellman[29] in 2003, Levy et al[27] in 1991 and **valentine et al in 1994** have found advantages to the routine use of two plates rather than one. However, other clinical results do not corroborate these clinical results and more elaborate biomechanical tests have failed to show the benefit of a second miniplate.

In 1994, Ellis and Walker[30] in their study used two noncompression miiplates in treating mandibular angle fracture observed very high rate of major complications (28%), mostly infections.

Shierle et al in 1997 and Siddiqui[31] et al 2007 stated that two plate fixation does not offer advantages over single-plate fixtion in the treatment of mandibular angle fractures. These results found that biomechanics are only one factor considered in fracture management. Other factors like limited dissection to maintain blood supply also important.

In a prospective study by **Ehrenfeld et al[32], in 1996** thre**e** groups were compared: one treated with MMF, another with intra oral AO 2.7-mm plates, and a third group treated with intra oral miniplates fixation and third molars in the fracture line were removed. The MMF group had the lowest complication rate, and the group treated with intraoral miniplate fixation encountered complication only in one patient. The authors concluded that smaller non compression plates lowered the complication rate.

The use of two points of fixation has been fraught with complications, as observed in the study by **Ellis[33] in 1999**, where he states that 'Whenever two points of fixation were used for fractures of the angle, the complication rate was much higher than when one point of fixation was applied . This high complication

rate has also been observed in other studies. Others have found no added advantage of two-plate fixation over single-plate fixation.

Edward Ellis and John Graham[34] 2002 examined the use of a 2.0-mm locking bone plate/screw system mandibular surgery. A total of 80 fractures in 59 patients were treated with the 2.0-mmlocking plate/screw system. They found that 2.0-mm locking plate/screw system is simple to use and provides sound fixation in all cases.

Ayman Chritah, Stewart K. Lazowand Julius R. Berger[35].,in 2005 assessed a Locking Miniplate/screw system in the treatment of mandibular fractures with a 1 week of maxillo mandibular fixation. They found locking plates placed along Champy's line of ideal osteosynthesis a reliable and effective treatment modality for mandibular fractures. Postsurgical MMF is beneficial in all mandible angle fracture patients. He concluded postoperative MMF performs several functions: MMF Helps to form an oral mucosal epithelial seal and allows undisturbed healing of incisions intraorally, Helps initially stabilize the occlusion, particularly in cases treated with non rigid fixation and trains the patient to become accustomed to a liquid diet. He found that even in the marginally cooperative patient, MMF helps the patient realize that behavior modification is necessary to achieve a good outcome and for those patients who are unreliable, arch bars and short-term fixation in place seem to encourage patients to return for follow-up examination.

Rudderman et al[25]., in 2008 pointed towards the significance of soft tissue in stabilization of the fracture and the existence of facial force circuits that transmit the force through bone, soft tissue, and activated muscle, as well as fascia.

In the study of **Mehra and Murad[36], in 2008**, 57 patients were treated with a single 4-hole non-compression plate at the lower border with satisfactory outcomes. In their study, postoperative MMF of 2 weeks followed by guiding elastics was used. They observed that a neutral compression miniplate at the inferior border did not cause any distraction of the superior border.

In **2010, Edward Ellis[37]** in his prospective 12 year study evaluated the outcomes of three treatment methods in patients with isolated mandibular angle fracture treated by, 1] Nonrigid fixation using interosseous wiring that includes 5 to 6 weeks MMF,2] Nonrigid but functionally stable fixation using a single miniplate and 3] Two miniplates. He concluded that single miniplate fixation is easiest internal fixation system to master and is associated with fewer complications than two other techniques.

Julie Kimsal et al[38] in 2011 in their finite element study on biomechanical analysis of mandibular angle fractures analized three fixation schemes, 1] 6 hole bicortical compression plate at the inferior border, 2] Single tension band at the superior border and 3] Both tension band at superior border and inferior border bicortical plate. This is the first known study to explore and confirm clinical observations of angle fracture fixation outcomes with a detailed biomechanical modeling. The results from this study support the use of the single tension band configuration as a less invasive fixation approach to fractures of the mandibular angle.

Daniel Cameron Braasch et al[12].,in 2013 in their study concluded that most commonly accepted technique for isolated mandibular angle fracture is a single

miniplates placed at the superior border. When angle fractures are associated with another mandibular fracture, the same technique can be used for the angle but preferably with rigid fixation of the other fracture or fractures. Routine use of postoperative antibiotics and removal of teeth in line of fracture is less advocated.

There are few studies involving the use of bioresorbable plates in the treatment of mandibular angle fractures. In vitro studies have shown no statistically significant difference in breaking and displacement forces when comparing 2.0-mm titanium plates and resorbable plates. Limited studies with small sample sizes have shown that bioresorbable plates can be used to successfully treat angle fractures, with no reports of malunion or nonunion. These studies also demonstrated a low complication rate with bioresorbable plates. Although these studies have shown the efficacy of bioresorbable plates, more studies are required before routine use is recommended[39,41].

Edward Ellis[40]in 2013 in his study concluded that the fixation requirements of patients treated with double fractures of the mandible are different than when treating isolated fractures of the mandible. Double fractures require that atleast one of the fractures undergoes rigid fixation to decrease the incidence of complications.

P.D.RiberoJunior, O.Magro-Filho[41] in 2014 in vitro evaluation of conventional and locking miniplates /screw systems for the treatment of mandibular fractures found locking plate/screw system provided significantly greater resistance to displacement than conventional ones. Locking Miniplates offered more resistance than conventional miniplate.

J. Rodrı´guez-Chessa, S. Olate et al[42]., in 2014 evaluated the bending resistance of metallic and resorbable plates and screws in a mandibular body fracture model. Forty polyurethane synthetic hemi mandibles were used. Bending resistance tests were done on a universal testing machine with a linear displacement speed of 1 mm/min, a cell load of 500 N, and a load cell on the lower central incisor or on the lower second premolar. Results were analyzed using the Student's t-test, with the significance level set at 5%. No statistically significant differences were observed between the groups studied, either in the analysis of the osteosynthesis materials or related to the load-bearing points. The variables of displacement and peak load did not present any significant differences. In this in vitro model of a mandibular body fracture, the mechanical behaviour of a resorbable osteosynthesis was similar to that of a titanium osteosynthesis.

EFFECT OF THIRD MOLARS ON MANDIBULAR ANGLE FRACTURES

Reitzik et al[43]., in 1978 in their study on experimental fractures of monkey mandibles showed that a mandible with unerupted third molars required 60% of force to fracture it than one with fully erupted third molars as more osseous space is occupied by the impacted third molar weakens the mandible.

Tevepaugh[44] et al in 1995 in their retrospective study demonstrated that patients with mandibular third molars are 3.8 times more likely to have angle fracture than patients without third molars.

Kober et al[45]., 2001 in his biomechanical study stated that if the angle is weakened by partially erupted mandibular third molar there is a decreased possibility of condylar fracture as the impact would be dissipated by angle

fractures. The results of this study agree with those of **Zhu et al in 2005 ;Duan and Zhangi et al[46]., in 2008**.

A biomechanical study by **Meisami et al[47].,in 2002**which suggested that mandibular resistance is maintained by the integrity of the cortical bone, not by the thickness of medullary bone; this means that the superficial position of the third molar breaks the integrity of the external oblique line to create a fragile point in the mandible.

In 2004,Halmos and Edward Ellis III[48] in their retrospective study concluded that presence of impacted mandibular third molar increases the risk of angle fracture by 2.8 times and also stated the position of impacted tooth had variable risk for angle fracture.

Thangavelu et al[49] in 2010 in their retrospective study observed highest incidence of angle fracture in class II, position B mesioangualr impacted third molars.

Gaddipati et al[50] in 2014 in their retrospective study on influence of impacted mandibular third molars on mandibular angle and condyle fractures stated that the presence of an impacted third molar increases the risk of mandibular angle fracture and reduces the risk of condyle fracture. They also observed that highest incidence of angle fracture was observed in position 'A' impacted mandibular third molars and there was no significant relationship exists in relation to position of third molar within the ramus and angulation of impacted mandibular third molars.

TEETH IN LINE OF FRACTURE

Historically, extraction of the tooth in the fracture line was advocated, as this was thought to decrease the risk of infection and the need for removal of the wisdom tooth and plating at a later date[51,52] .

A nonrandomized prospective study conducted by **Rai et al[53]** stated that the removal of third molar causes a loss of contact and continuity in the fracture and more chances of displacement or collapse during fixation. Schwenzer et al and Kruger et al recommended that a completely impacted third molar which does not impede the reduction of the fracture fragments can be left in place.

Shetty et al[54] in 1989 in his review states that third molars with grossly carious lesion which cannot be restored, loose or unstable tooth , periapical or pericoronal infection, tooth or root fracture, pathology associated with third molar tooth and tooth which prevents adequate fracture reduction should be removed. They also states that complete bony impacted third molar can be left in place to provide a larger repositioning surface.

Pavan M.Patil[55] in 2013 in his prospective study states that there is no statistically significant increase in risk of postoperative complications when tooth in fracture line is retained and its removal may not decrease complication rates in angle fractures. Third molars should be retained within the line of fracture whenever possible unless removal is clinically indicated.

SURGICAL APPROACHES

The surgical approach has been another point of controversy, with some advocating the intraoral approach, others the extra oral approach, and others a combination approach.

In **1954, Shira**[56] described an intraoral approach for mandibular angle fractures involving a tooth in the fracture line. **Bradley**[57] **in 1954** also reported favourable experience with transoral stainless steel transosseous wiring in fractured mandibular angle treatment.

In the study by **Toma et al**[58] **in 2003,** reported no significant difference in the complication rate between the transoral and extra-oral routes for treatment of mandibular body, angle, and ramus fractures. They also found that when the surgeon shifted from the intraoral approach to the extraoral approach intraoperatively, the complication rates increased and recommends preoperative decision making is important on surgical approach.

Sugar et al[59]**, In 2009** concluded at the clinical sequelae of the transoral and transbuccal techniques. He found a statistically significant lower incidence of plate removal in the transbuccal group (20%) versus the transoral group (36%) and less breakdown of the wound at the surgical site in the transbuccal group (9%) versus the transoral group.

Kale TP et al[60] **in 2010** stated that transbuccl approach gives promising results in terms of facial nerve function and esthetics. They also stated that transbuccal approach requires less operating time when compared with extraoral approach but requires special armamentarium and is technique sensitive.

S. Laverick et al[61], in 2012, proposed that transbuccal plating leads to fewer plates being removed for infection than ridge plating in the treatment of angle fractures. Transbuccal plating is no more time consuming than ridge plating and there is no significant scarring or facial nerve damage associated with the transbuccal approach.

Wan K et al[44]., in 2012, He concluded that, use of the trans buccal technique produces fewer postoperative complications compared with the trans oral technique[62].

COMPLICATIONS

The reported incidence of minor and major complications in the literature varies widely, but minor complications constitute the majority. Minor complication, such as localized infections, wound dehiscence, hardware exposure, and plate loosening, are frequently related to each other. These complications are generally managed by removal of the loose screws and plate. When they occur in the early postoperative period, however, they can often be managed by placing the patient on oral antibiotics and chlorhexidine rinses. In addition, maxillo mandibular fixation can be used to further stabilize the fracture until healing occurs. If swelling or drainage continues after the healing period is complete, the screws and plate then can be removed under local anesthesia in the office.

Higher percentages of postoperative infection were found by **Ellis et al [63], in 2002** in his prospective study, both in cases of toot removal and maintenance where the tooth was in the line of mandibular angle fracture without a statistically significant difference between the two procedures. **Baykul et al[64].,in2004 and**

Marker et al [65].,in 1994 did not find any connection between the time elapsed from trauma to treatment and the occurrence of postoperative infection , though their studies involved different mandibular fracture sites and did not specifically determine the procedure that was used to deal with the tooth present in the fracture line at each treatment period .

Maloney et al[66]., in 2011 believed that the presence of a tooth in the line of fracture exposes the fracture, providing a channel for the introduction of bacteria; however, their data show that when the fracture undergoes early immobilization in patients who have fixation, appropriate diet, and antibiotics, neither retention nor extraction of the tooth in the line of fracture will play a statistically significant role as a source of complication.

Major complications are uncommon after treatment of mandibular angle fractures, especially with the use of single miniplate fixation. These complications are more common with the use of two miniplates, extraoral placement, and use of an inferior border plate and bicortical screws. Potential treatment options include simple removal of the existing hardware and debridement of the necrotic and infected bone. More extensive treatment may be required, however, including resetting the fracture and applying new internal fixation. If a large defect remains after debridement, bone grafting is required.

Mehra P et al[67]., in 2008 conducted a study involving a retrospective analysis of mandibular angle fracture patients treated at Boston Medical Center from 1999 to 2006. Mandibular angle fractures can be successfully treated with both rigid extraoral and intraoral semirigid fixation techniques. Greater visualization and

more control of fractured segments can be obtained with extraoral access, but the risk of facial-nerve injury and the possibility of objectionable scarring are significantly greater. Intraoral approach with semirigid fixation technique has a low rate of complications, is relatively simple, and decreases operating room-related costs.

THREE DIMENSIONAL MINIPLATES

The shortcomings of rigid and semi-rigid fixation led to the development of 3 dimensional (3D) miniplates which consists of two 4 hole miniplates joined by four interconnecting cross struts. Unlike compression and reconstruction plates their stability is not derived from the thickness of the plate. With the screws fixed monocortically to the outer cortical plate, these rectangular plates form a cuboid which possess 3D stability. The 3D plating system is based upon the principle of obtaining support through geometrically stable configuration. The Quadrangle geometry of plates assures a good stability in three dimensions of the fracture sites since it offers good resistance against torque forces.

Farmand and Dupoireux[68] in 1992 developed the concept of 3D miniplates. Their shape is based on the principle of the quadrangle as a geometrically stable configuration for support. Since the stability achieved by the geometric shape of these plates surpasses the standard miniplates, the thickness can be reduced to 1 mm. The 3D miniplates itself was a misnomer as the plates themselves were not 3-dimensional, but holds the fracture segments rigidly by resisting the 3-dimensional forces namely shearing, bending and torsional forces acting at the fracture site in function.

Wittenberg et al[69].,in 1997 in a biomechanical study used 3-D plates for fixation of mandibular angle fractures concluded that they are easy to place intraorally and provides adequate fixation for mandibular angle fractures.

Guimond et al[6]., in **2005** reported that percutaneous fixation of noncomminuted mandibular angle fracture with curved 2.0mm strut plate carries low morbidity and low infection rate of 5.4% comparable with reconstruction plates.

Feledy et al[70]., in 2004 reported in their study found that matrix strut plate provides greater resistance to out-of-plane movement through strut bars and prevents torsional at the fracture site and also reported 9% infection rate

Zix et al[71]., in **2007** in his clinical study using straight or curved 3D plate in mandibular angle fracture management, reported 0% infection rate in their study. They emphasized that strut plate have some hardware-related advantages over conventional miniplates and reconstruction plates. They are easy application and easy adaptation without fracture displacement or distortion and simultaneous stabilization at both superior and inferior borders

Jain et al[72]., in 2010 in his clinical study found that 3-D plates have an advantage of simplified adaptation to the bone without distortion or displacement of the fracture, as well as the simultaneous stabilization at both the superior and inferior borders, making the 3-D miniplates a time saving alternative to conventional mini plates.

Mahmoud E. Khalifa et al[73]., in **2012** concluded that 3D miniplate system is a better and easier method for fixation of mandibular fractures, compared with the

conventional miniplate. The 3D miniplate system provides good stability in most cases and operative time is shorter because of simultaneous stabilization at both superior and inferior borders. But there is limitation to use in cases of oblique fractures and those involving the mental nerve as well as there is excessive implant material because of the extra vertical bars incorporated for countering the torque forces.

In an in vitro biomechanical study **Alkan et al[74] in 2007, in** fresh sheep hemi-mandibles assessed the stability of a mandibular angle fracture using Champy's technique, dual miniplates either in monoplanar or biplanar fixation or 3D strut plate. They concluded that 3 D strut plate is superior to champy's single miniplate and monoplanar dual miniplates in resisting compressive forces in the mandibular angle fracture.

These findings are in accordance with those of studies that have previously reported the placement of a 3D strut plate or biplanar plate to have favourable biomechanical behaviour. In addition to providing greater stability when subjected to lateral displacing forces, it can be postulated that this new design of miniplate will also offer a plating technique with a simple intraoral approach and few major complications, such as facial nerve injury or visible scar tissue. The placement of a six- or eight hole 3D miniplate or two separate miniplates for fixing mandibular angle fractures is more difficult and will most often require a transbuccal approach.

Bui et al [75]., in 2009 concluded that the use of 2.0-mm 8-hole curved strut plate in the treatment of uncomplicated mandbular angle fracture is associated with a

low infection rate (8.2%). The infection rate for those mandibular angle fractures with teeth in the line of fracture retained was 14% compared with 5.6% for those fractures with the teeth in the line of fracture extracted. The clinical studies with three dimensional plates reported low complication rates and concluded that the 3-D miniplates used are the alternatives to conventional miniplates for the treatment of mandibular fracture.

Malhotra et al[76]., in 2012, conducted a study in 20 patients with mandibular fracture to evaluate the versatility of titanium 3D plate in comparison with conventional titanium miniplate fixation. The patients were evaluated for the clinical assessment of mobility after fixation, pre and post-surgical occlusal relationship, adequacy of reduction on post operative radiograph and any post surgical complications. The 3D plating system was found to be advantageous over conventional miniplates. The system is reliable and effective treatment modality for mandibular fractures.

Balakrishnan et al[77]., in 2014 in a study concluded the advantages of 3D plating systems. They are- minimal tissue dissection near the osteotomy and fracture line, fixation point remains in vicinity of osteotomy line, stability of the 3-D plate obtained by its configuration not by thickness or length, blood supply to the fragments is not disturbed and adjustments are easy because of thin connecting arms of the plate.

According to **Sawatari et al[78] in 2016**, the design of the strut plates has significant advantages over single plate and two-plate fixation methods on the lateral surface of the mandible. Literature mentions the mandible on functional

loading creates zone of tension and compression. The stability of 3D plates were conferred by the vertical strut components. If 3D plate is appropriatey positioned, resistance to the tensile forces created at the superior horizontal plate is distributed and conducted through the vertical struts to the inferior horizontal plate. Conversely, the inferior plate transmits the compressive forces through the same vertical struts to superior plate. This opposing force conduction provides the stability of the 3D strut plate in angle fracture of mandible. The resistant forces produced by masticatory muscles are not reliant on the tensile and compressive strength of the single linear plate, but are distributed throughout the entire surface area that the plate covers. Due to the interconnected design, all the forces are transmitted along the combined length of the horizontal parallel bars and vertical struts. The literature further documents that, the strut plate provides more torsional stability and greater resistance against gap formation along the inferior border.

SURGICAL ANATOMY

Mandible is a tubular bone which is bent into a blunt V-shape. Like all tubular bones, the strength of the mandible resides in the dense cortical plates. The cortical bone is thicker anteriorly and at the lower border of the mandible but the lower border is relatively thin posteriorly [79].

The mandible depends mainly on the inferior alveolar alveolar artery in the first year of life[80]. Later, periosteal vascularization increasingly takes over. In adults mandible depends entirely on the periosteum for its blood supply[81]. Periosteal stripping should be minimal duing surgical procedure to preserve the blood supply.

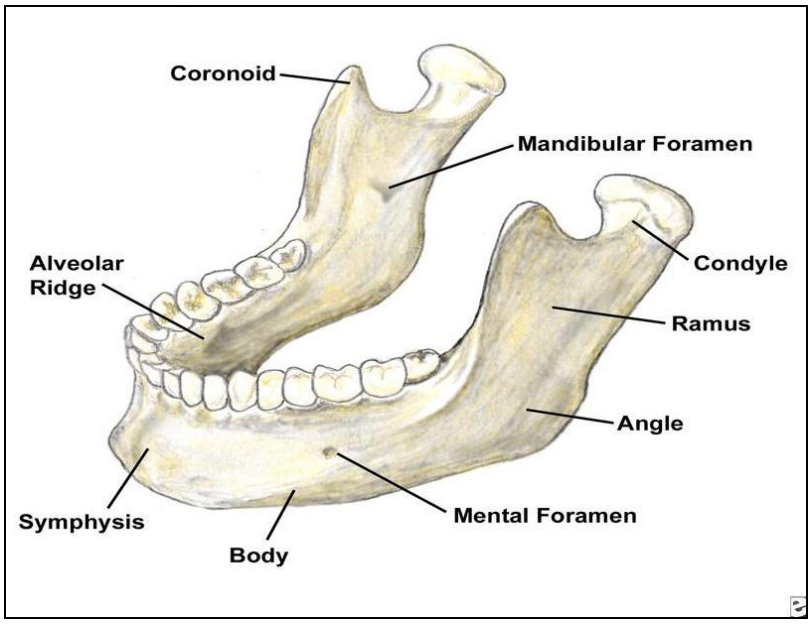


Figure 1. Anatomy of mandible

The basic V-shape is modified by the functional processes namely angle, coronoid process and alveolar process. On the lateral surface of ramus masseter muscle is attached and medial pterygoid muscle gains its attachment on the medial

surface of the ramus. Temporalis muscle is attached to the tip and anterior border of the coronoid process. The alveolar bone forms around the developing teeth and supports the tooth roots after eruption.

The mandible is weak in the lingual surface in relation to second and third molar teeth where tensile strain is more from forces applied force on the same side. The weakness is produced by abrupt change in direction between body and ascending ramus in two planes. In vertical plane change in direction is almost 20° while in horizontal plane 70° at the upper border. This is due to lack of conformity between the curve of U shaped alveolar process and the diverge mandibular rami.

Major structural forces are created at the angle of the mandible, because of the cantilevered nature of its shape. The height of the bone at the angle of mandible is critical in determining its strength and the presence of the perfectly aligned muscle sling created by the masseter and medial pterygoid muscles. Thus, aging, with its potential for bone and alveolar resorption, weakens this area. Weakest areas in the mandible includes, the area lateral to the mental protuberance, mental foramen, mandibular angle, and condylar neck. Impacted or unerupted teeth creates a zone of weakness. Bones in children are so resilient and flexible which reduces the chances of fracture even in the prescence of unerupted teeth[82].

Inferior alveolar nerve

The inferior alveolar nerve is a branch of mandibular nerve. It enters the the mandibular canal behind the lingula and runs in a concave course to reach the mental foramen. From back to front it runs closer to the outer cortex and to the

lower border. It is 8–10mm away from the lower border of the mandible at its lowest point. The average thickness of the cortex in that region is 5mm. Sometimes it may be less than 3mm[83] .

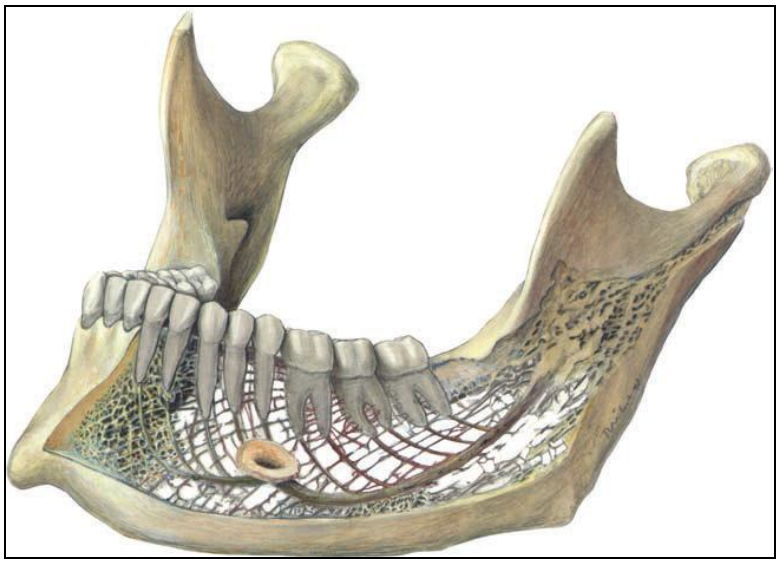


Figure 2. Course of inferior alveolar nerve in mandibular canal

Inferior alveolar canal turns upwards and forwards at about 1 cm before the mental foramen[82,83]. The mental foramen lies approximately midway between the alveolar crest and the lower border on a vertical line corresponding to the first or second premolar. In the mandibular canal the neurovascular bundle surrounded by a bony tunnel .In some cases its bony structure around the inferior alveolar nerve is poorly developed[82].

Facial Vessels

The facial artery and vein are usually not encountered during the intra oral approach unless dissection through the periosteum occurs in the region of the mandibular ante gonial notch. The facial artery originates from the external carotid artery in the carotid triangle. It is crossed by posterior belly of the digastric muscle, the stylohyoid muscles, and the hypoglossal nerve near its origin.

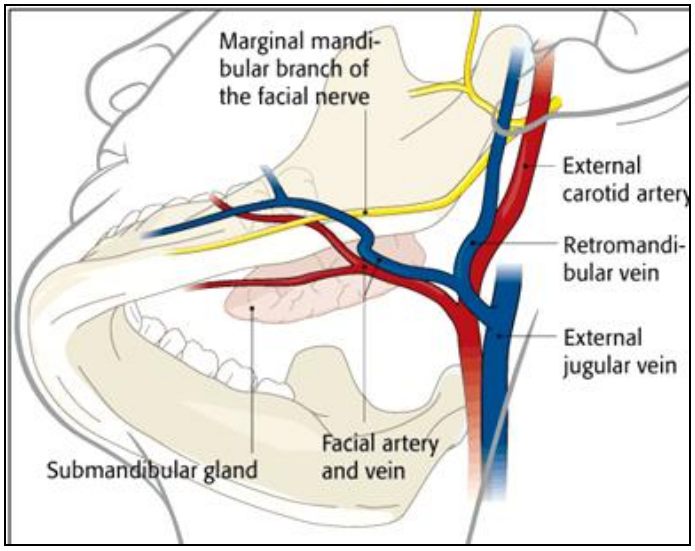


Figure 3.Course of facial artery and vein.

In the submandibular triangle, the facial artery ascends deep to the submandibular gland, grooving its deep and superior aspect, and then passes superficially to reach the inferior border of the mandible. At the anterior border of the masseter muscle, facial artery crosses the mandible and is related to skin and platysma in its superficial surface. Facial artery can be palpated at the anterior border of mandible.

The facial vein drains the angular and ultimately labial vessels. It lies more posterior and superficial to the artery. The facial artery and vein are close to the mandible in the region of the inferior border. The only structure that separates the vessels from the bone is the periosteum[84].

Biomechanics in the angle of mandible

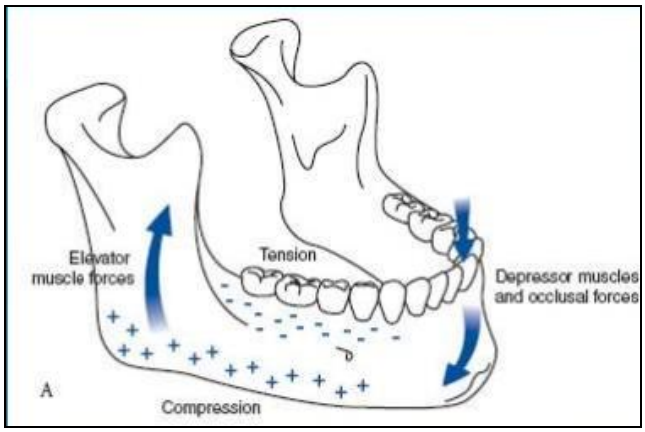


Figure 4.forces exerted on mandible during function

In mandible tensile force is created at the superior border which corresponds to the external oblique ridge and mandibualr alveolus and compressive force created at the inferior border by the action of elevators and depressor muscles of mandible. In between superior and inferior borders neutral zone present at the level of inferior alveolar nerve. In fractured mandibular angle separation present at the superior border and reduction present at the inferior border under function[82].

Ideal Osteosynthesis Line on the Mandible

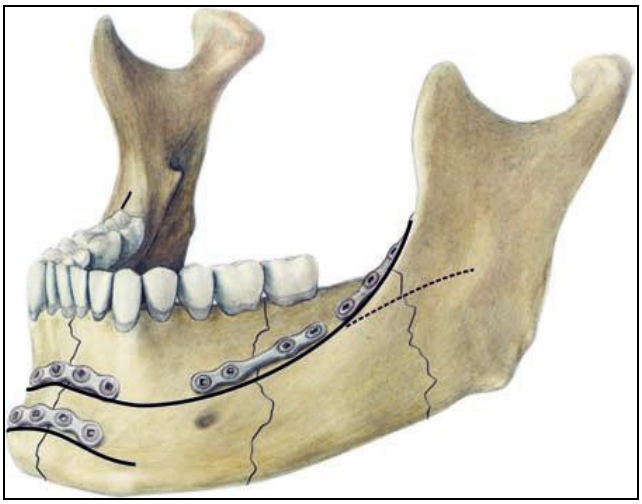


Figure 5. Champy's Ideal lines of osteosynthesis lines on the mandible

The line corresponds to the course of a tension line at the base of the alveolar process inferior to the root apices. In that region a plate can be fixed with monocortical screws, as follows: behind the mental foramina the plate is applied immediately below the dental roots and above the inferior alveolar nerve at the angle of the jaw the plate is placed ideally on the inner broad surface of the external oblique line; if this has been destroyed, the plate is fixed on the external cortex as high as possible, in the anterior region, between the mental foramina, in addition to the subapical plate, another plate near the lower border of the mandible is necessary to neutralize the torsion forces[82].

MATERIALS AND METHODS

The study population was selected from the outpatient section of the Department of Oral and Maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital, Chennai, with isolated, unilateral fracture of angle of the mandible based on the following criteria.

INCLUSION CRITERIA

a. Unilateral isolated angle fractures of mandible.
b. Simple and compound fractures.
c. Angle fractures with deranged occlusion.
d. Patients between 20-45 years of age group.
e. Dentulous patients.

EXCLUSION CRITERIA

a. Comminuted angle fractures.
b. Patients with systemic disorders and immunocompromised patients.
c. Edentulous patients.
d. Infected fractures

STUDY DESIGN: Prospective clinical trial

SAMPLE SIZE: 10

Selected patients were divided randomly into two groups containing five patients in each group for open reduction and internal fixation. All patients were treated under local anesthesia.

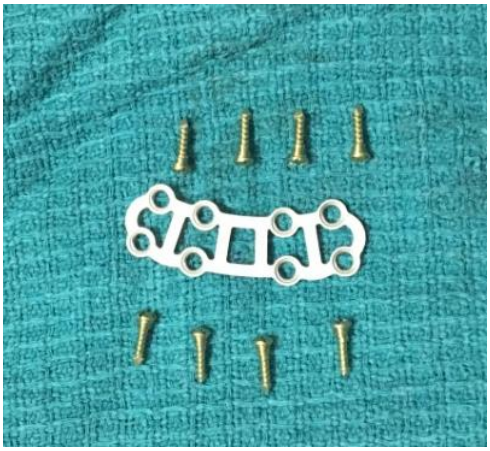
Group I: Five patients were treated with a single 2 x 4 hole conventional titanium miniplates and four 2 x 8 mm titanium screws.

Group II: Five patients were treated with single 2x8 hole 3-dimensional curved strut titanium miniplates and eight 2 x 8 mm titanium screws using transbuccal trocar and cannula system.

Ethical approval for this study was obtained from the Institutional Ethical Committee and informed consent obtained from each patient both in English and patients mother tongue explaining the nature of the surgical procedure and the study and its possible outcomes.

Patients were clinically examined and preoperative occlusion and neurosensory deficit were recorded. Clinical photographs of both preoperative and postoperative occlusion were taken. Preoperative radiographs were taken.

3-D CURVED STRUT MINIPLATE



4 HOLE MINIPLATE

ARMAMENTARIUM

The following parameters are evaluated

i. Surgical accessibility
ii. Adaptability of plates
iii. Intra operative time
iv. Stability of fracture fragments
v. Occlusal discrepancy
vi. Wound infection and dehiscence
vii. Neurosensory deficit
viii. Fracture healing

Accessibility of surgical site, adaptability of plates, time taken for the procedure and fracture fragment stability were assessed intraoperatively. Orthopantomogram was taken 1 week after ORIF to assess the position of fractured fragments and at 3 and 6 month period to assess the fracture healing. During the follow-up period the occlusion, fragment stability, presence or absence of wound infection and wound dehiscence if any and neurosensory deficit were assessed.

Neurosensory deficit of lingual nerve, mental nerve and inferior alveolar nerve were assessed pre-operatively for anaesthesia, paresthesia, tingling sensation, and normal sensation by light touch and one point discrimination, and then compared with post-operative results.

SURGICAL PROCEDURES

1. **PREPARATION**

The patient is painted using povidone iodine both intraorally and extraorally and draped taking sterile aseptic precautions.

2. **INJECTION OF LOCAL ANESTHETIC AND VASOCONSTRICTOR**

Local anesthesia containing 2% Lignocaine with 1:200000 adrenaline is injected into the oral mucosa, sub mucosa and facial muscle. Submucosal injection of a vasoconstrictor can dramatically reduce the haemorrhage during incision and dissection.

3. **INCISION**

Incision is made with No. 15 Bard Parker blade. The incision is placed beginning on the anterior border of the ascending ramus at the level of maxillary occlusal plane. The buccal portion of the buccal fat pad is usually not more inferior than occlusal plane. Placement of the incision at this level may spare severing the buccal artery and nerve, though damaging them is more a nuisance than a clinical problem. Then the incision was carried down along the lateral portion of the anterior ramus and along the oblique line continued forward approximately 5mm from the mucogingival junction and extended upto the first molar tooth. The length of the incision depends on the fracture site.

Leaving unattached mucosa on the alveolus facilitates closure. Incision traverses the mucosa, submucosa, facial muscles and periosteum. This incision provides good exposure to the mandibular angle region. In patients requiring third molar removal, an extended third molar crevicular incision placed.

3a. **INCISION FOR TRANSBUCCAL APPROACH**

A small extraoral stab incision was given to permit the insertion of transbuccal cannula. The location of stab incision was guided by the location of the fracture line and the position of facial vessels. Then blunt dissection done to perforate the mandibular periosteum and trocar was advanced through the dissected channel into the operative site at the area of plate fixation.

The shape and design of the trocar ensures that it displaces vital structures such as nerves and vessels away without damaging it. The cheek retractor was applied which helps in stabilizing the trocar assembly during movement towards and away from the fracture site.

4. **EXPOSURE AND REDUCTION OF THE FRACTURE**

Subperiosteal dissection done to expose the fracture site. Fracture fragments were reduced under direct vision. Satisfactory occlusion was achieved and IMF was performed.

6.**FIXATION**

In group I, internal fixation was carried out using standard titanium miniplates and monocortical screws in the superior border along champy's osteosynthesis lines.

In group II, internal fixation was done on the lateral surface of the mandible with the struts parallel to the fracture line with three dimensional titanium curved strut plates and monocortical screws by combined intraoral and transbuccal approach.

7. WOUND CLOSURE

The surgical site was irrigated with povidone iodine and saline. Intraoral wound closed by simple interrupted suturing with resorbable 3-0 Vicryl. The pass of the needle should grab the mucosa, sub mucosa and the muscles. The extraoral stab incision was closed layerwise with 3-0 Vicryl and 3-0 Ethilon/ Prolene. Extraoral compression dressing is applied over the surgical site such that it avoids the dead space formation and to maintain the position of the repositioned facial muscles.

8. IMMEDIATE POST-OPERATIVE PHASE

Patient is kept under observation for an hour and vitals monitored. Patient is noted for post-surgical bleeding. The patient is started on intravenous antibiotic (Cefotaxime 1 g and Metrogyl 500 mg), intravenous glucocorticosteroid (Dexamethasone 8 mg) tapered after 2 days and intramuscular NSAID (Diclofenac 75 mg) administered for a period of five days. The patient is advised to avoid pressure over the cheek on the operated side. Liquid diet is recommended for the IMF period of one week. The patient was advised to come for follow-up on a regular basis.

FOLLOW-UP AND OBSERVATION

All the patients were evaluated:

1. First post operative day.
2. One week post operatively.
3. Second week post operatively.
4. Fourth week postoperatively.
5. Six month postoperatively.

GROUP I

STEP 1-INCISION

STEP 2-EXPOSURE

STEP 3-REDUCTION AND FIXATION

STEP 4-WOUND CLOSURE

GROUP II

STEP 1-INCISION

STEP 2-EXPOSURE

STEP 3-EXTRAORAL STAB ICISION

STEP 4-APPLICATION OF TROCAR AND CANNULA

STEP 5-REDUCTION AND FIXATION

STEP6-INTR ORAL WOUND CLOSURE

STEP 7-EXTRA ORAL WOUND CLOSURE

CASE REPORTS

(ONE SAMPLE IN EACH GROUP HAS BEEN DISPLAYED)

GROUP I

PATIENT‟S NAME : Mrs. Muthazhagi

AGE/ SEX : 23/F

CHIEF COMPLAINT: Pain and swelling in his left side lower jaw and inability to clench teeth for past 3 days

HISTORY: Alleged history of assault 2 days back.

GENERAL EXAMINATION

Patient is moderately built and nourished

No signs of anemia, cyanosis, clubbing, ictreus, pedal edema or peripheral lymphadenopathy.

CLINICAL FINDINGS

- Diffuse swelling present in left angle of mandible and is tender on palpation.
- Bilateral condylar movements- palpable.
- Mouth opening -restricted
- Occlusion- deranged
- Tenderness and step present in left angle of mandible behind second molar teeth.

RADIOGRAPHIC FINDINGS

OPG reveals fracture line in left angle of mandible distal to 37 and mesial to 38.

DIAGNOSIS

Left mandibular angle fracture.

TREATMENT

Open reduction and internal fixation using four hole straight titanium miniplates and 2x 8 mm titanium screws under local anesthesia.

GROUP II

PATIENT‟S NAME : Mr. Raja

AGE/ SEX : 43/ M

CHIEF COMPLAINT: Pain and swelling in left side face since trauma

HISTORY: Alleged history of RTA four days back.

GENERAL EXAMINATION

Patient is moderately built and nourished

No signs of anemia, cyanosis, clubbing, ictreus, pedal edema or peripheral lymphadenopathy.

CLINICAL FINDINGS

- Diffuse swelling present in left angle of mandible and is tender on palpation.
- Bilateral condylar movements- palpable.
- Mouth opening -restricted
- Occlusion- deranged
- Step present in left angle of mandible behind second molar teeth.

INVESTIGATIONS

OPG- showed well defined radiolucent line distal to 38

DIAGNOSIS:

Left angle fracture of mandible.

TREATMENT

Open reduction and internal fixation using three dimensional curved strut titanium miniplates and 2x 8 mm titanium screws.

CASE REPORTS

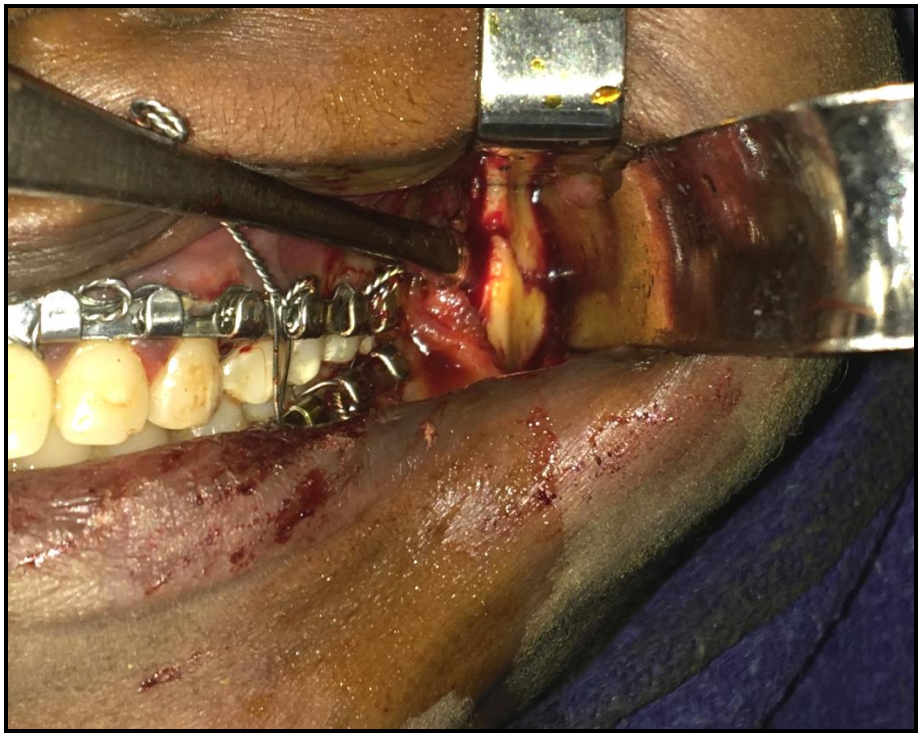
GROUP I

PRE OP PHOTOGRAPH

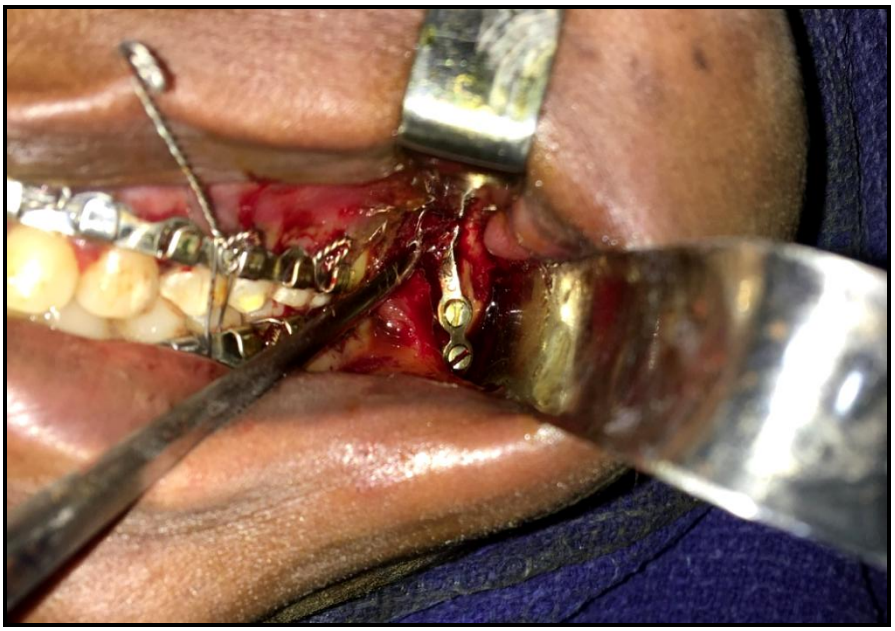
PRE OP OCCLUSION

PRE OP OPG

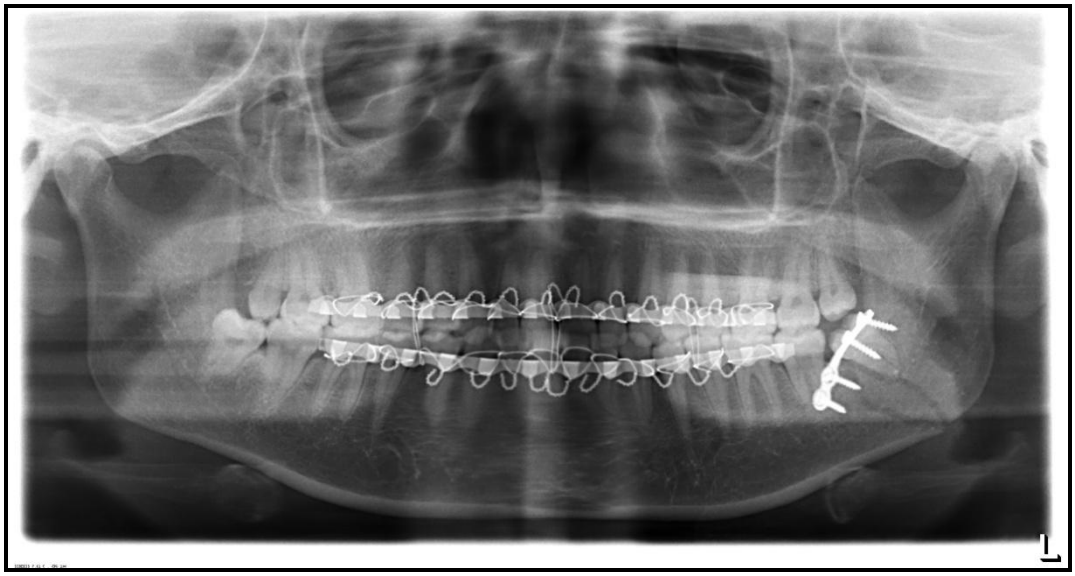
EXPOSURE



FIXATION



POST OP OPG



POST OP PHOTOGRAPH

POST OP OCCLUSION

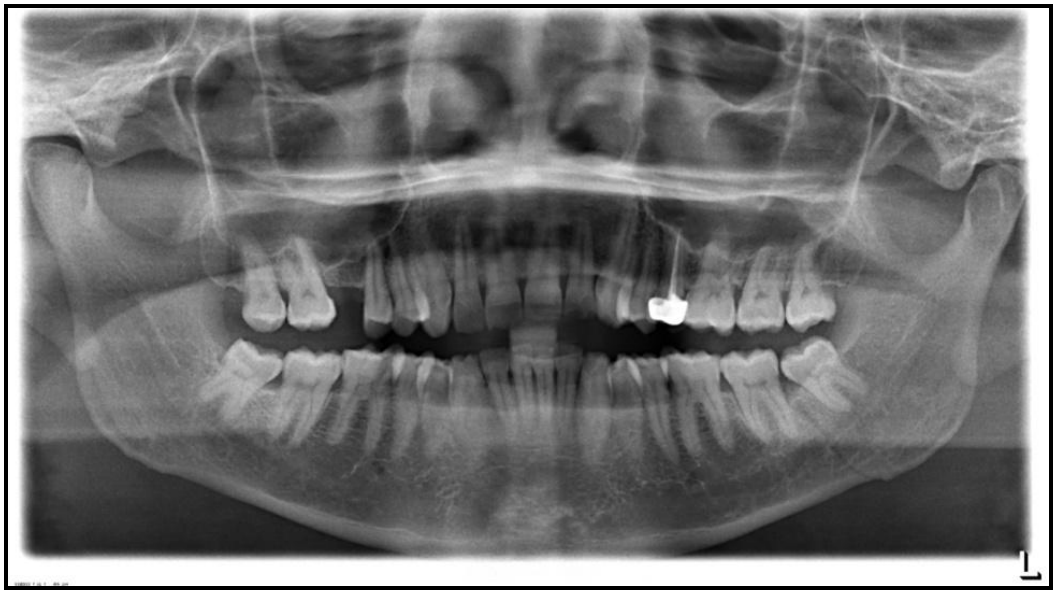
POST OP OPG AFTER 6 MONTHS

GROUP II

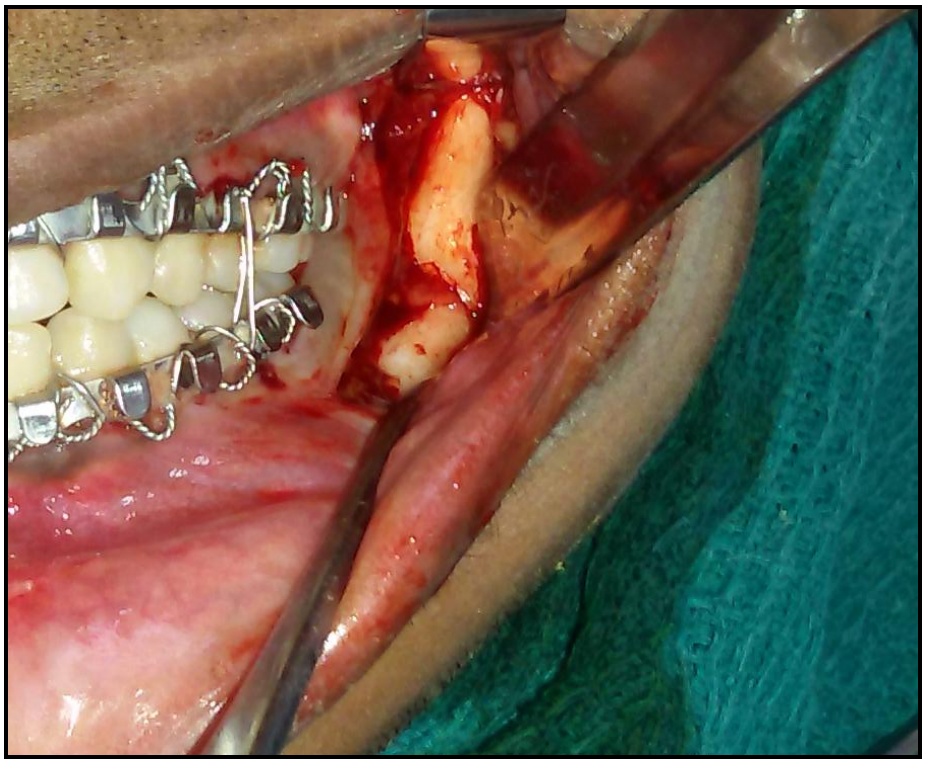
PRE OP PHOTOGRAPH

PRE OP OCCLUSION

PRE OP OPG

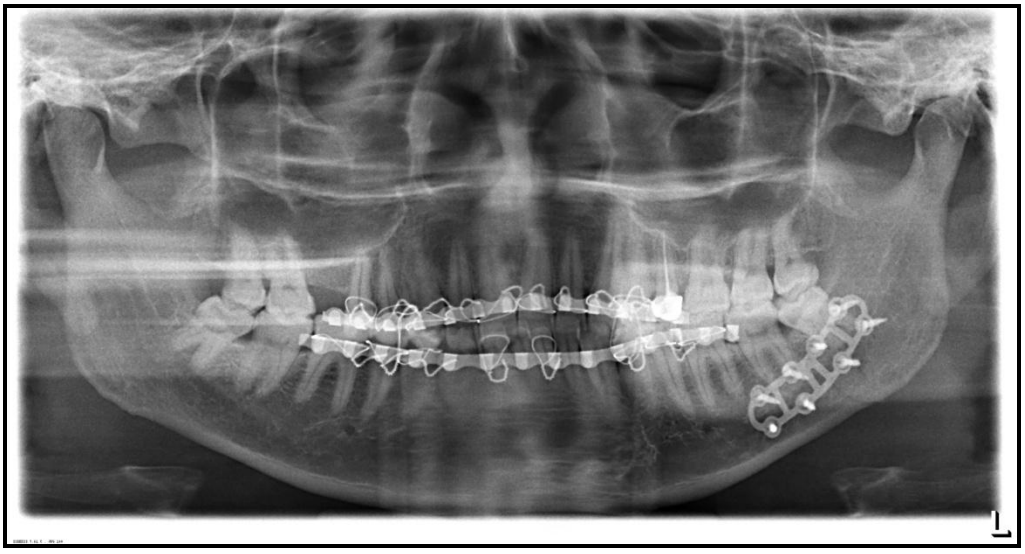


EXPOSURE



FIXATION

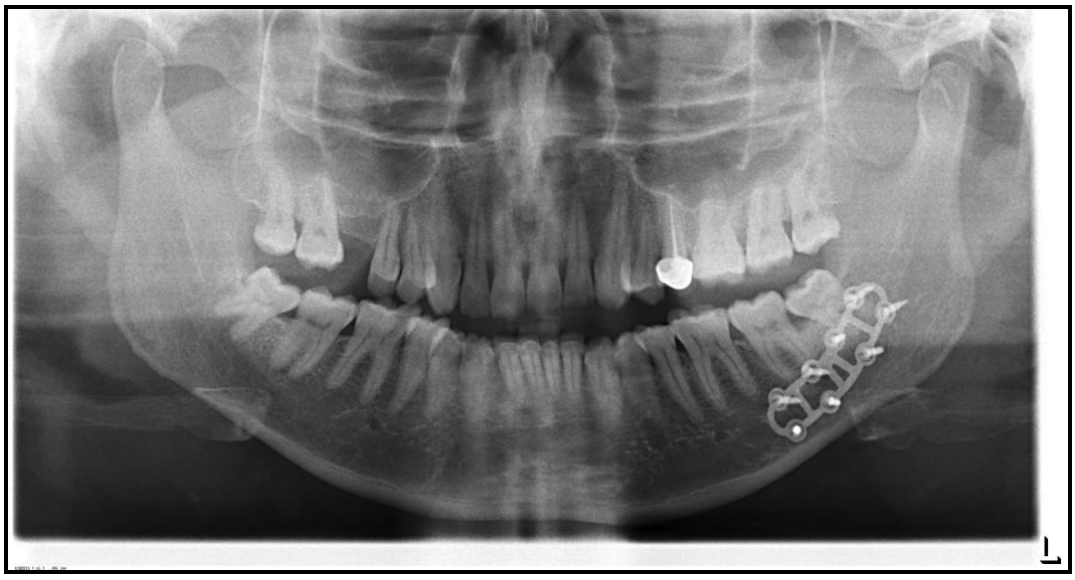
OPG AFTER ONE WEEK



POSTOP PHOTOGRAPH

POST OP OCCLUSION

OPG AFTER SIX MONTHS



OBSERVATIONS AND RESULTS

This was a prospective clinical and radiological study involving a total of 10 patients with isolated unilateral angle fractures of mandible, who were divided randomly into two groups.

- Group I- ORIF under LA using 2 x 4 hole straight titanium miniplate and 2x 8 mm monocortical screws [n=5].
- Group II-ORIF under LA using 2x8 hole curved strut titanium miniplate and 2x8 mm monocortical screws [n=5].

Out of 10 cases, 3 were females (30%) and 7 were male (70%), 6 left angle fracture (60 %) and 4 right angle fracture(40%) . The etiology of trauma was road traffic accident in six cases (60%) and assault in four cases (40%).

Swelling, pain and inability to chew were the chief complaints in all the patients. The angle fracture was horizontally unfavorable in 60% of the cases and minimally displaced in 40% of patients in both group I and II. Third molar was involved in fracture line in 7 cases (70%) and 3 patients had root fracture (30%) and were removed at the time of surgery.

All patients in this study were followed up at 1,2,4 weeks and every month thereafter for a period of 6 months postoperatively.

The parameters assessed were,

- Surgical accessibility
- Adaptability of plates
- Intra operative time
- Stability of fracture fragments
- Occlusal discrepancy
- Wound infection and dehiscence
- Neurosensory deficit
- Fracture healing

STATISTICAL ANALYSIS:

Software used: SPSS, Version 16.0

Table 1.Concept of P value

P Value	**Level of significance**
0.000 to 0.010	Highly significant
0.011 to 0.050	Significant
0.051 to 1.000	Not significant
If the P value is .000 then put as <0.001.	

SURGICAL ACCESSIBILITY

SCORE

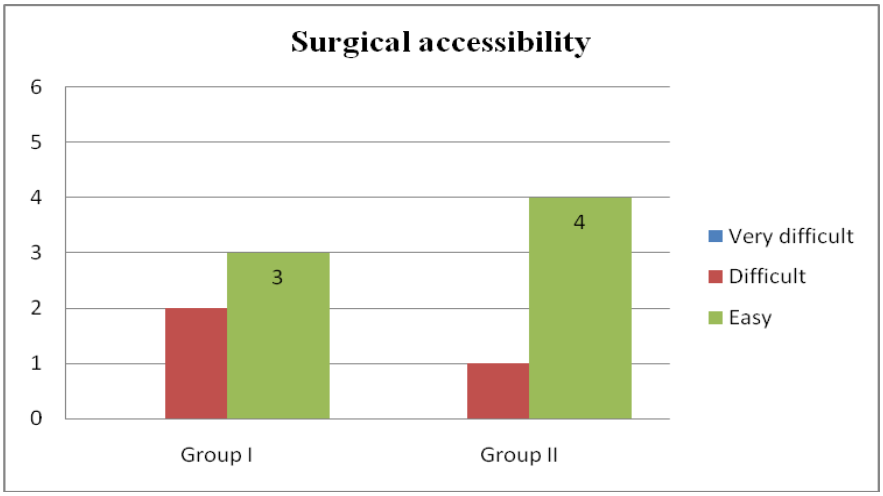
- Very Difficult -1
- Difficult -2
- Easy -3

Table No.2 surgical accessibility

Accessibility	Group I	Group II	P value
Very difficult	0.0 %	0.0%	0.4*
Difficult	40%	20%	
Easy	60%	80%	

*Pearson chi-square

In group I, 40% patients had easy accessibility and 60% patients had difficult accessibility. In group II, 80% patients had easy accessibility and only 20% had difficult accessibility. P value [0.4] shows no statistically significant difference in between the groups.



ADAPTABILITY OF PLATES:

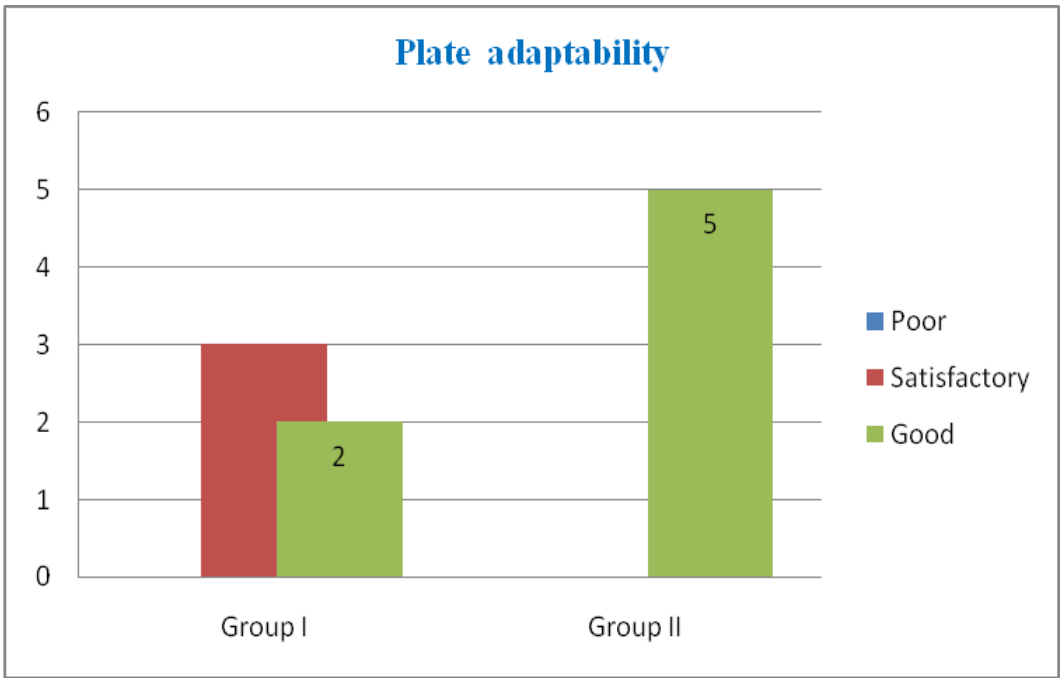
SCORE:

- Poor adaptability - 1
- Satisfactory adaptability - 2
- Good adaptability - 3

Table No.3 Plate adaptability

Plate adatability	Group I	GROUP II	P value
Poor	0.0 %	0.0%	**0.038***
Satisfactory	60%	0.0%	
Good	40%	100%	

*Pearson chi-square



The adaptability of plates was good in 40% of patients in group I and 60% of patients it was satisfactory. In group II all (100%) patients had good plate adaptability. The **P-value [0.038]** shows statistically significant difference in intergroup level.

INTRAOPERATIVE TIME

Duration of surgery was measured in minutes from placement of incision to closure of the wound. The mean intraoperative time in Group I was 55minutes; standard deviation ± 7.9 minutes and in Group II it was 73 minutes; standard deviation ±5.7 minutes. On an average, the intraoperative time was 18 minutes more in group II patients than in Group I. P value 0.003.

Table No.4 Intraoperative time

	Group	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**P value**
Intra operative time	Group 1	5	55.0000	7.90569	3.53553	**0.003***
	Group 2	5	73.0000	5.70088	2.54951	

*Independent Sample t Test

STABILITY OF FRACTURE FRAGMENTS

SCORE:

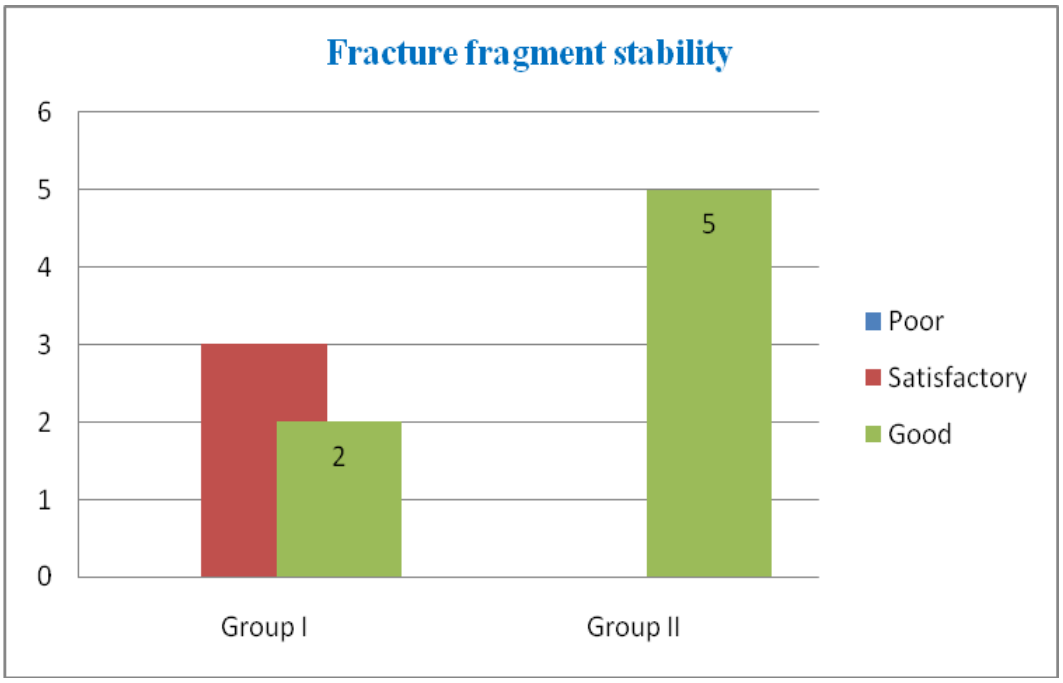
- Poor stability - 1
- Satisfactory stability - 2
- Good stability - 3

Table No.5 Fragment stability

Fragment Stability	**Group I**	**Group II**	**P value**
Poor	0.0 %	0.0%	**0.038***
Satisfactory	60%	0.0%	
Good	40%	100%	

*Pearson chi-square

In group I, stability of fractured fragments after fixation was good in 60% of patients and satisfactory in 40% of patients. In group II, all patients (100%) had good fragment stability. The **P value (0.038)** shows statistically significant difference in intergroup level.



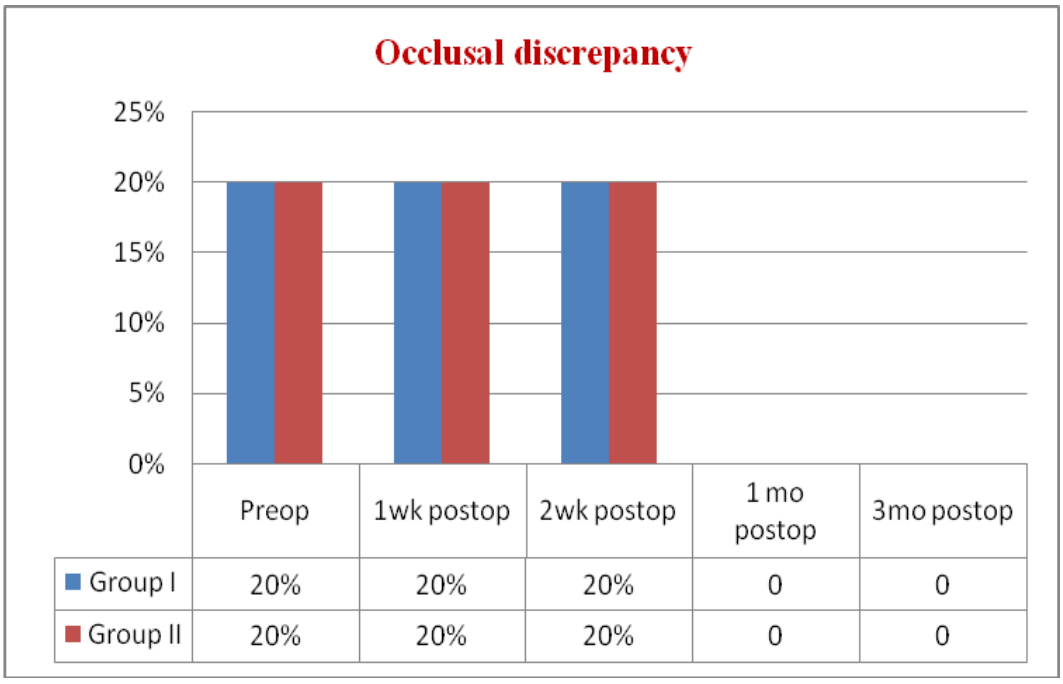
OCCLUSAL DISCREPANCY

All patients included in this study had preoperative occlusal discrepancy. Mild occlusal discrepancy was observed in one patient in group I (n=1) immediately after plate fixation and was successfully managed by guiding elastics for a period of 10 days. No patient showed occlusal discrepancy at the end of 2 weeks and no occlusal discrepancy was noted in both the groups in the follow-up period of 6 months. The **P value [0.001]** shows statistically significant difference.

Table No.6 Occlusal discrepancy

Group	Pre op	Immediate Postop	1 week postop	2 week postop	1month postop	6 month Postop	P value
GROUP I	100%	20%	20%	0%	0%	0%	**0.001***
GROUPII	100%	0%	0%	0%	0%	0%	

*Pearson Chi-Square test



NEUROSENSORY DEFICIT

SCORE

- Present -1
- Absent - 2

Neurosensory deficit of lingual nerve, mental nerve and inferior alveolar nerve were assessed pre-operatively for anaesthesia, paresthesia, tingling

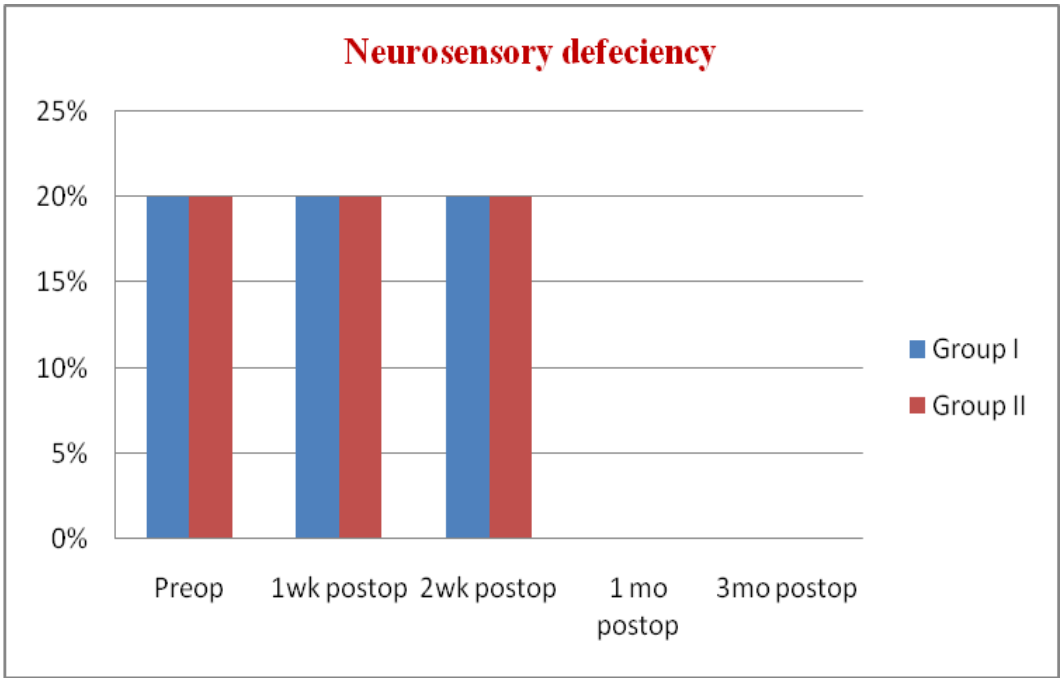
sensation, and normal sensation by light touch and one point discrimination, and then compared with post-operative results.

Table No.7 Neurosensory deficit

Group	Pre op	1 week postop	2 week postop	1 month postop	3month postop	6 month Postop	P value
Group I	20%	20%	20%	20%	0.0%	0.0%	0.001*
Group II	20%	20%	20%	20%	00.%	0.0%	

*Pearson Chi-Square test

One patient in each group had preoperative inferior alveolar nerve paresthesia. Paresthesia persisted upto 1 month postoperatively and completely recovered by three months.



WOUND INFECTION AND DEHISCENCE

In the follow-up period no postoperative wound infection or dehiscence was observed in both the groups.

SCORE

- Present – 1
- Absent - 2

Table No. 8 wound infection and dehiscence

Group	Pre-op	1week post op	2 week post op	1 month post op	3 month Post op	6 month postop
Group I	2	2	2	2	2	2
Group II	2	2	2	2	2	2

FRACTURE HEALING

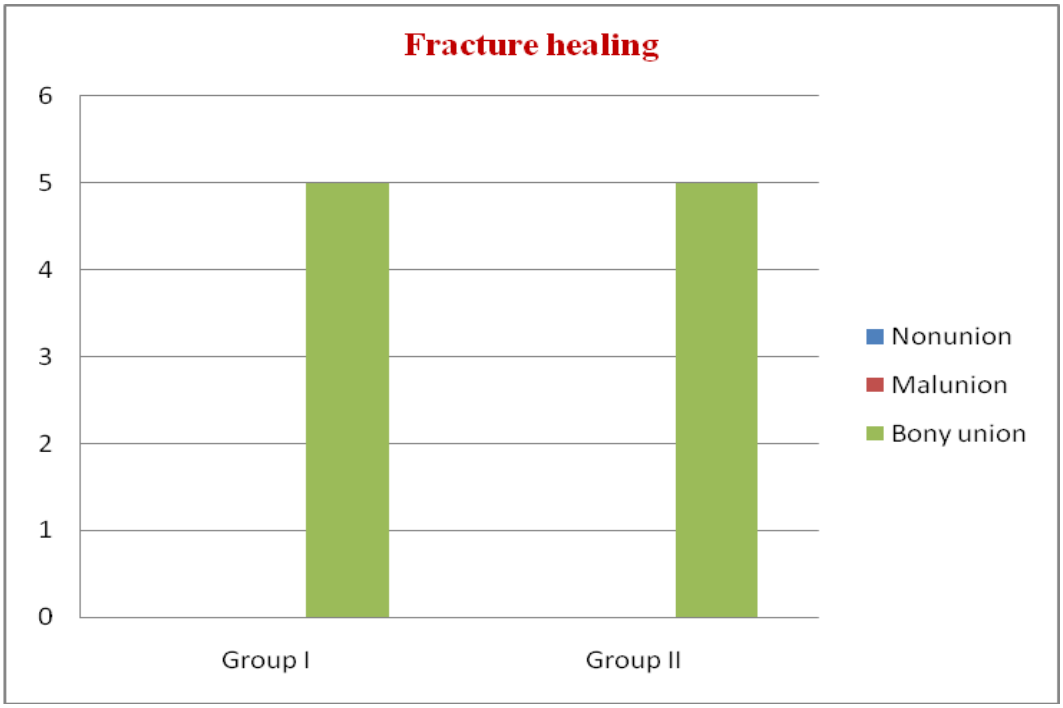
SCORE

- Nonunion - 1
- Malunion - 2
- Bonyunion – 3

Fracture healing was assessed radiographically using Orthopantomogram. At the end of follow-up period of 6 months all patients (100%) in both the groups had good fracture healing with a score of 3.

Table No. 9 Fracture healing

Group	Non union	Malunion	Bony union	P value
Group I	**0%**	**0%**	**100%**	**-**
Group II	**0%**	**0%**	**100%**	



DISCUSSION

Complex biomechanics in the region of mandibular angle, thin cross sectional area, presence of third molar and abrupt change in shape from horizontal body to vertical ramus makes angle region more vulnerable to fracture and the management becomes more difficult[12].

The treatment goal includes restoration of anatomical configuration, preinjury occlusion, masticatory efficiency and fracture repair with minimal complications and disabilities during the treatment period[85].

The lack of definite understanding on the complex biomechanics in mandibular angle resulted in numerous treatment modalities from conservative management to open reduction. Fracture osteosynthesis is widely considered standard treatment of mandibular angle fractures. Inspite of a great deal of research, well established treatment protocols for the mandibular angle fracture remains controversial[86,] .

Most commonly used technique for ORIF in noncomminuted angle fracture involves placing a single miniplate at the superior border as recommended by Champy's. It requires a more conservative dissection, less periosteal stripping and tissue stretching[87].

Based on both clinical and biomechanical studies single plate at the superior border allows the fracture line open at the inferior border. This subtle displacement can lead to subsequent displacement on lateral surface and posterior open bite[74,88].

Mostafa Farmand and Dupoireux[68] in 1992 developed the concept of 3Dimensional plating in which stability is achieved by its closed geometric configuration which resists forces in all three dimensions, namely shearing, bending and torsional forces. The stability in 3 dimensional plating is gained over a defined surface area and is achieved by its configuration not by the plate thickness. Large free areas between plate arms and minimal dissection permit good blood supply to the bone.

Feledly[70] et al, in his biomechanical study found that matrix strut miniplate provides greater resistance to out of plane movements through strut bars and prevents torsional forces at the fracture site. As matrix strut plate length and design allows placement of 4 screws on either side of fracture offers good stability.

In this prospective study, out of ten patients with isolated unilateral angle fractures of mandible, five patients were included in group I, were treated with four hole titanium miniplate in superior border as recommended by champy's and compared with five patients in group II, were treated using 8 hole 3 dimensional curved strut miniplate placed on lateral surface of mandible.

Various surgical approaches are used in the management of angle fractures. In highly displaced angle fractures, extraoral approach gives good accessibility and proximal fragment control compared to the intra oral route[58]. The extraoral approach will often cause an unesthetic scar and risk of injury to marginal mandibular branch of the facial nerve.

Intra oral approach offers simultaneous control of the occlusion and repositioning of the fragments during the surgery, and direct visualization of the occlusion during placement of bone plates or wires. The advantages of an intra oral approach are avoidance of an external scar and facial nerve injury. The disadvantages are possibility of infection and plate exposure as thin soft tissue coverage over the plate and greater degree of plate bending required to adapt to the complex bone contour leads to plate breakage[62].

In transbuccal approach fracture site exposure and reduction done primarily by intraoral approach and a small percutaneous stab incision given and transbuccal trocar inserted to facilitate plating in the lateral surface of mandible. The advantages are excellent visibility and accessibility, no injury to marginal mandibular branch of facial nerve and inconspicuous scar[60]. **Wan et al** states that out of 227 one patient developed hypertrophic scar[62].

In this present study intraoral approach was preferred in conventional plate fixation at the superior border in group I and transbuccal approach was preferred in 3-dimensional curved strut plate fixation on the lateral surface of mandibular angle region in group II. No facial scarring or facial nerve injury was observed in group II. Similar results were observed by **Sugar[59] et al .**

Shetty[54] et al in his review states that third molars with grossly carious lesion which cannot be restored, loose or unstable tooth, tooth with periapical or pericoronal infection, tooth or root fracture, pathology associated with third molar tooth and tooth which prevents adequate fracture reduction should be removed. They also states that third molar with complete bony impaction can be left in place to provide a larger repositioning surface. In this study 3 patients (30%) had root fracture in third molar in line of fracture and were removed at the time of surgery.

Duration of surgery was measured from the start of incision to closure of the wound. In this study it was observed that patients in Group II required 18-min more than patients in Group I. As the 3-dimensional strut plate is large and four more screws has to be placed to secure the plate in group II when compared with group I intraoperative time is more in group II. This finding coincides with the study of **Feledy[70] et al., Almorasi[87] et al** who conducted a study on the time taken for the treatment of angle fractures.

Guimond[6] et al, Feledy[70] et al emphasized that strut plates have some hardware related advantages over conventional miniplates and reconstruction plates. They are easy application, simplified adaptation to the bone and simultaneous stabilization at both the superior and inferior borders. Similar results were observed in present study.

In this study, 80% of patients had easy accessibility in group II and only 60% patients had easy accessibility in group I. As transbuccal trocar and cannula was used to fix plates in group II, accessibility was better than in group I.

Adaptability of plates was assessed clinically by visualizing the gap between the bone contour and the plates. In this study, all patients (100%) in Group II had good plate adaptability and only 40% of patients in Group I had good plate adaptability. Plate adaptability was found to be significantly superior in group II with **a P value of 0.038**. This was explained by **Sawatari[78] et al,** that lateral surface of mandible in angle region is generally flat without significant convexity and concavities, 3-Dimensional curved strut plate can be fixed without significant contouring and also states, if need arises the plate must be contoured adequately to adapt the plate passively.

Stability of fractured fragments after fixation produces a stable foundation and improved vascularity to the area which helps in better wound healing. In this present study, it was observed that three patients in group I had immediate postoperative mobility at the fractured site which persisted and later decreased over a period of 4 weeks. By the end of two months, none of the patients had mobility in fractured segments. All patients(100%) in group II showed good fragment stability from the immediate postoperative period. In this study, 3-dimensional curved strut titanium miniplate demonstrated significant stability of fractured fragments with **P-value (0.038)** less than 0.05 when compared to 4 hole conventional straight titanium miniplate. **Wittenberg[69] et al** found that the gap and displacement values for 3D plates were comparable with reconstruction plates.

MMF helps to initially stabilize the occlusion, particularly in cases treated with non rigid fixation and trains the patient to become accustomed to a liquid diet. He found that even in the marginally cooperative patient, MMF helps the patient realize that behavior modification is necessary to achieve a good outcome and for those patients who are unreliable, arch bars and short-term fixation in place seem to encourage patients to return for follow-up examination[35].

The occlusion of patients was checked preoperatively and during the follow up visits after surgery. All patients included in this study had occlusal discrepancy preoperatively. Mild occlusal discrepancy was observed in one patient immediately after plate fixation in group I and was managed successfully by guiding elastics for a period of 10 days. No occlusal discrepancy was noted in group II. By the end of 2 weeks, pretraumatic occlusion was achieved and no

occlusal discrepancy was observed thereafter. The **P value (0.001)** is statistically significant. These findings were in accordance with **Pandey[89] et al.**

Sensory alterations are often observed in mandibular fractures. **T**he literature shows that the main cause of sensory alterations in mandibular angle fractures is the degree of displacement of the fracture [90]. **Thurmuller[91] et al** 2001, reported the incidence of preoperative IAN paresthesia in a wide range of 5.4%-58% and the persistence of sensory loss is 0.9%-66.7%. **Zix[71] et al 2007** states 75% sensory disturbance related to trauma and 25% were caused by treatment. Post treatment sensory disturbance is due to fracture manipulation rather than drilling and screw placement close to the nerve. He also reported that the nerve function recovered within first three months.

In this present study, one patient in each group had paresthesia in the region of inferior alveolar nerve distribution in the preoperative period. Paresthesia persisted upto one month postoperatively and both patients regained inferior alveolar nerve sensation completely by the end of three months. Thereafter no sensory alteration was noted. No surgically induced paresthesia was noted in this study.

Edward Ellis III & Walker[30] observed 16 % complications after single plate fixation in superior border at the external oblique ridge in angle fracture management. **Guimond[6] et al 2005** in his study concluded that 3 dimensional plates have low infection rate of 5.4%. Similar result of 5.6% infection rate was observed when teeth in line of fracture were removed by **Bui[75] et al, 2009**.

In this study, none of the patients presented wound infection or dehiscence for the follow-up period of 6 months. Plate fixation in both the group requires minimal soft dissection and minimal periosteal stripping which helps to maintain good blood supply and subsequent soft tissue and bone healing.

Radiographic examination at the first postoperative month revealed no changes in the position of the fractured segments and the fracture lines are hardly detected. At the end of the follow up period of 6 months, fracture line could not be detected on the radiographs and none of the patients showed any signs of malunion or nonunion in both the groups. No signs of radiolucency were seen around the screws. No external callus was detected in the both groups. At the end of follow-up period of 6 months, fracture healing was good in all patients in both the groups.

In this study, none of the patient showed plate fracture, contrary with **Zix[71] et al**. who observed hardware failure with strut plates in 5% of patients and also states that multiple plate bending and improper plate placement and insufficient fracture reduction are the possible reasons for hardware failure.

3-Dimensional curved sturt titanium miniplate used in this study provides good plate adaptability, easy accessibility to the surgical site and three dimensional stability in the management of isolated unilateral mandibular angle fractures than four hole straight titanium miniplate. There were no incidence of surgically created neurosensory deficit, wound infection and dehiscence in both these plating systems. The small sample size and limited follow-up period could be considered as the limitation of this study.

SUMMARY AND CONCLUSION

Clinical and biomechanical studies shows that single plate fixation at the superior border in mandibular angle fracture allows the fracture line to open at the inferior border. This subtle displacement can lead to subsequent displacement on the lateral surface and posterior open bite.

The concept of 3-Dimensional plating is established by Mostafa Farmand [7] and Dupoireux in 1992, in which stability is achieved by its closed geometric configuration which holds the fracture segments rigidly by resisting forces in all three dimensions namely shearing, bending and torsional forces during functional movements.

In this prospective study, a total of 10 patients with isolated unilateral angle fractures of mandible, were divided randomly into two groups. In group I, five patients were treated by ORIF using four hole straight titanium miniplate and monocortical titanium screws. In group II five patients were treated with eight hole 3-dimensional curved strut titanium miniplate and monocortical titanium screws. Patients in both the groups were followed up at 1,2,4 weeks and every month thereafter for a period of 6 months postoperatively. The parameters assessed were occlusal derangement, neurosensory deficit, adaptability of the plates, operating time, surgical site accessibility and fragment stability, fracture healing, wound infection and dehiscence .

The results showed that the plate adaptability and fragment stability was superior in patients treated with 8 hole 3- dimensional curved strut miniplate when compared to conventional four hole straight miniplate. Though no significant

statistical difference was found between the two groups, surgical accessibility was better in group II. All patients in this study had preoperative occlusal discrepancy. Mild occlusal discrepancy was observed in one patient in Group I immediately after plate fixation and was successfully managed by guiding elastics for a period of 10 days. No occlusal discrepancy was noted in group II postoperatively. None of the patients showed occlusal discrepancy by the end of second postoperative week. One patient in each group had inferior alveolar nerve paresthesia in the preoperative period. Paresthesia persisted upto one month postoperatively and both patients regained sensation completely by three months. Radiographic examination at the first postoperative month revealed no changes in the position of the fractured segments and the fracture lines are hardly visible. At the end of the follow-up period of 6 months fracture healing was satisfactory with no evidence of malunion or nonunion in both the groups. There were no incidence of surgically created neurosensory deficit, wound infection and dehiscence in both these plating systems.

The 3 dimensional curved strut titanium miniplate was found to be standard in profile, strong yet malleable, facilitating reduction and stabilization at both the superior and inferior borders. This plate seems to be an easy alternative to conventional champy's miniplates. The surgical technique and instrumentation used in this study were in accordance with the established technique of miniplates osteosynthesis. All patients in this study appreciated early recovery of normal jaw function, uneventful healing and good union at the fracture site with minimal weight loss due to early reinstatement of the masticatory function.

Based on the above findings, it can be concluded that 3-Dimensional curved sturt titanium miniplate offers superior plate adaptability and fracture fragment stability than conventional four hole titanium miniplate in the management of unilateral isolated mandibular angle fractures without any significantly different overall complication rate. The small sample size and limited follow-up could be considered as the limitations of this study.

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ANNEXURE I

CASE REPORT FORM

A COMPARATIVE STUDY OF 3-D CURVED STRUT MINIPLATE VERSUS FOUR HOLE MINIPLATE IN OPEN REDUCTION AND INTERNAL FIXATION OF ISOLATED UNILATERAL ANGLE FRACTURES OF MANDIBLE

Patient's Name : _____

Age/ Sex : _____

_____

Patient's Identification No : _____

_____

Contact Address : _____

Contact No :

Institution : TN Govt. Dental College & Hospital,

Chennai - 600 003.

Centre : Dept. of Oral & Maxillofacial Surgery,

TN. Govt. Dental College and Hospital

Chennai - 600 003.

Patient'sIdentification/ O PNo : _____ Date: _____

Details of Surgery

Procedure followed : Open reduction and internal fixation under local anaesthesia

Duration of Surgery :

Any other information :

Details of Drug therapy :

Name of the Investigator :

Signature of Investigator :

ANNEXURE II

CASE SHEET

A COMPARATIVE STUDY OF 3-D CURVED STRUT MINIPLATE VERSUS FOUR HOLE MINIPLATE IN OPEN REDUCTION AND INTERNAL FIXATION OF ISOLATED UNILATERAL ANGLE FRACTURES OF MANDIBLE

PATIENT'S NAME : _____

AGE/ SEX : _____

PATIENT'S : _____

IDENTIFICATION NO : _____

CONTACT ADDRESS : _____

_____

CONTACT No : _____

INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.

CENTRE : Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003.

GROUP I/ GROUPII :

CHIEF COMPLAINT :

HISTORY:

CLINICAL FINDINGS:

INVESTIGATIONS:

TREATMENT:

Procedure followed : Open reduction and Internal fixation under local anaesthesia

Duration of surgery :

FOLLOW UP

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR

ANNEXURE III

INFORMED CONSENT FORM

A COMPARITIVE STUDY OF 3-D CURVED STRUT MINIPLATE VERSUS FOUR HOLE MINIPLATE FOR OPEN REDUCTION AND INTERNAL FIXATION OF ISOLATED UNILATERAL ANGLE FRACTURES OF MANDIBLE

Participant ID No:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care."

Date	Name of the participant	Signature/thumb impression of the participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

_____

_____

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date	Name of the witness	Signature of the witness

Date	Name of the interviewer	Signature of the interviewer

ANNEXURE IV

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு

கீழ்தாடை எலும்பு முறிவிற்கான டைட்டானியத்தால் செய்யப்பட்ட நான்கு துளைகள் உடைய பிளேட்டிங்கையும், டைட்டானியத்தால் செய்யப்பட்ட எட்டுதுளைகள் உடைய வளைந்த ஸ்டிரட்பிளேட்டிங்கையும் ஒப்பிடும் ஆய்வு.

பெயர் புற நோயாளி எண்
வயது / பால் ஆராய்ச்சி சேர்க்கை எண்

முகவரி

தொலைபேசி எண்:

நான்.....வயது.....என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக் கொள்ள ஒப்புதல் அளிக்கிறேன்.

பின்வரும் நிபந்தனைகளை நான் ஏற்றுக்கொள்கிறேன்.

- நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் செயல்முறைகள் பற்றி முழுவதுமாக தெரிவிக்கப்பட்டுள்ளேன்.
- எனது உடைந்த கீழ்தாடை எலும்பு டைட்டானியத்தால் செய்யப்பட்ட நான்கு துளைகள் உடைய பிளேட் அல்லது டைட்டானியத்தால் செய்யப்பட்ட எட்டுதுளைகள் உடைய வளைந்த ஸ்டிரட்பிளேட் கன்னத்தில் சிறிய துளையிட்டு டிரோகார் மூலம் பொருத்தப்படடு சரிசெய்யப்படும் என அறிவேன்.
- எனது உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான அறிகுறிகள் தென்படடாலோ அதற்கு சிகிச்சை பெற்றுக்கொள்வதற்கும் முழு உரிமை உள்ளதாக அறிகிறேன்.
- நான் ஏற்கெனவே உட்கொண்ட மற்றும் உட்கொள்கின்ற மருந்துகளின் விவரங்களை ஆராய்ச்சியாளரிடம் தெரிவித்துள்ளேன்.
- என் மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்துவதற்கு சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும் ,ஆராய்ச்சியாளரும் என்னுடைய அனைத்து விவரங்களையும் இரகசியமாக வைத்திருப்பதாக அறிகிறேன்.

....
நோயாளியின் பெயர் கையொப்பம் தேதி

....
ஆராய்ச்சியாளரின் பெயர் கையொப்பம் தேதி